

EXHIBIT A

IN THE COURT OF COMMON PLEAS OF ALLEGHENY COUNTY, PENNSYLVANIA

CIVIL DIVISION

No: G.D. 18-009823

Code: 004

KEISHA WISE, AMY DANISAVICH, :
MARIE COLLINS HUGHES, MARSHA :
CREASEY, AMBER HEDGES, MARY :
POWELL, KATHERINE LUCERO, :
TYNISHA ELLISON, ANGELIQUE :
ABDUL-MATIN, STEPHANIE :
FERNANDEZ, TRESSA SHIELDS, :
MAIDA URIBE, CRYSTAL ADAMS, :
JOYANNA EDGE, AMY OLSON, :
RACHAEL JOHNSON, BETTY KILLY, :
AMBER RIGGS, CONNIE HARRIS, :
MICHELLE THOMAS, MICHELLE :
SIEBER, JENNIFER CARLSON, :
LAKESHIA EDWARDS, TIESHA :
MOSLEY, KRISTY SILVERS, :
MICHELLE BRANHAM, ELIZABETH :
CLAAR, TASCHA FARNSWORTH, :
TAMIKA JACKSON, JAMIE :
KAMBARIAN, SHAMICA JONES, :
SHEENA MACKEY, MARIA LOPEZ, :
BRITTANY VEIT, JODI WHITE, :
AMBER ESPINOZA, AMY RUTAN, :
DONNA BAEZA, RACHEL SIMPSON, :
AMANDA SULLIVAN, DARRIELL :
CLEMENTS, NANCY RIVERA, :
CHRISTINE SCHMIDT, SHABRETA :
TERRELL, LILYBETT MARTIR, :
SHERRI HELMS, RAEMARIE :
COLEMAN, TARA DAUGHERTY, :
CHELSEA DEYARMIN, JACKIE :
MEYER, BOBBY HERNANDEZ, :
TABITHA ROSS, SARAH WALKER, :
LINDA SANTE :

Plaintiffs

v.

COMPLAINT IN A CIVIL ACTION

JURY TRIAL DEMANDED

Filed on behalf of Plaintiff

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Defendants.	:	

:

Defendants.

NOTICE TO DEFEND

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER [OR CANNOT AFFORD ONE], GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW [TO FIND OUT WHERE YOU CAN GET LEGAL HELP]. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

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TABLE OF CONTENTS

COMPLAINT IN A CIVIL ACTION	2
I. INTRODUCTION	2
II. PARTIES	8
A. PLAINTIFFS.	8
B. DEFENDANTS.	15
III. JURISDICTION AND VENUE	17
IV. FACTS	21
A. DESCRIPTION OF ESSURE® AND HOW IT WORKS.	21
B. MEDICAL DEVICE REGULATORY FRAMEWORK.....	23
1. Class III Medical Device Pre-Market Approval Requirements.	25
2. General Reporting Duties to the FDA are Required After the PMA Process.	27
3. A Manufacturer Must Follow Current Good Manufacturing Practices.	31
4. PMA Supplements for Labeling Changes.....	33
5. The FDA Prohibits Misleading or False Promotion and Marketing.	34
6. Violations of Federal Statutes or FDA Regulations Void the Federal Preemption Defense.	35
C. CONCEPTUS DEPENDED SOLELY ON ESSURE® SALES TO FIX THEIR PROBLEMS WITH MASSIVE DEBT AND ACHIEVE PROFITABILITY.....	37
D. MANIPULATING SAFETY INFORMATION ALLOWED CONCEPTUS TO BECOME A VIABLE COMPANY.....	38
E. CONCEPTUS AND BAYER CONTINUOUSLY SPREAD FALSE AND MISLEADING INFORMATION TO ALTER PERCEPTIONS OF ESSURE®'S SAFETY RISKS.	41
F. CONCEPTUS AND BAYER HAVE ALWAYS KNOWN THAT ESSURE® IS DANGEROUS.	43
1. Conceptus Was Charged with Early Regulatory Violations.....	43
2. Conceptus Knew About a Myriad Of Manufacturing Problems.	44
3. Conceptus Concealed Thousands of Migration and Perforation Reports From the FDA.	45
4. Conceptus Demonstrated a Continuing Pattern of Concealing Safety Complaints.	48
5. Trends in FDA Reports Prove That Conceptus and Bayer Withheld an Enormous Amount of Safety Information.	49

6. Bayer Misled the FDA About Rates of Essure® Breaking.	52
7. Now the Medical Community Is Discovering What Conceptus And Bayer Knew For Years: Essure® Is Dangerous.	53
8. The Revelation of Safety Information in the Public Leads to the Inevitable: FDA Mandates Major Changes to Essure® Sales.	57
G. CONCEPTUS' AND BAYER'S PARTICIPATION IN THE COVERING UP OF AND FAILURE TO ADEQUATELY WARN OF SERIOUS ADVERSE EVENTS AND INCREASED RISKS AND COMPLICATIONS ASSOCIATED WITH ESSURE® CAUSED PLAINTIFFS' INJURIES.	64
V. EQUITABLE TOLLING/FRAUDULENT CONCEALMENT	66
VI. GENERAL ALLEGATIONS	67
Representations	68
Causation	69
Damages	70
VII. SPECIFIC PLAINTIFFS' ALLEGATIONS	71
A. KEISHA WISE	71
1. Initial Essure® Procedure:	71
2. Post Essure® Procedure Condition and Treatment:	71
B. AMY DANISAVICH	74
1. Initial Essure® Procedure:	74
2. Post Essure® Procedure Condition and Treatment:	74
C. JACKIE MEYER.....	76
1. Initial Essure® Procedure:	76
2. Post Essure® Procedure Condition and Treatment:	77
D. CHELSEA DEYARMIN	78
1. Initial Essure® Procedure:	78
2. Post Essure® Procedure Condition and Treatment:	79
E. RAEMARIE COLEMAN	79
1. Initial Essure® Procedure:	79
2. Post Essure® Procedure Condition and Treatment:	80
F. TARA DAUGHERTY	81
1. Initial Essure® Procedure:	81
2. Post Essure® Procedure Condition and Treatment:	81
G. CRYSTAL ADAMS.....	82
1. Initial Essure® Procedure:	82
2. Post Essure® Procedure Condition and Treatment:	82

H.	LILYBETT MARTIR	84
	1. Initial Essure® Procedure:	84
	2. Post Essure® Procedure Condition and Treatment:	84
I.	MARIE COLLINS HUGHES.....	85
	1. Initial Essure® Procedure:	85
	2. Post Essure® Procedure Condition and Treatment:	86
J.	MARSHA CREASEY	87
	1. Initial Essure® Procedure:	87
	2. Post Essure® Procedure Condition and Treatment:	87
K.	AMBER HEDGES.....	89
	1. Initial Essure® Procedure:	89
	2. Post Essure® Procedure Condition and Treatment:	89
L.	MARY POWELL	90
	1. Initial Essure® Procedure:	90
	2. Post Essure® Procedure Condition and Treatment:	90
M.	KATHERINE LUCERO	91
	1. Initial Essure® Procedure:	91
	2. Post Essure® Procedure Condition and Treatment:	92
N.	TYNISHA ELLISON.....	94
	1. Initial Essure® Procedure:	94
	2. Post Essure® Procedure Condition and Treatment:	94
O.	ANGELIQUE ABDUL-MATIN.....	96
	1. Initial Essure® Procedure:	96
	2. Post Essure® Procedure Condition and Treatment:	96
P.	STEPHANIE FERNANDEZ.....	98
	1. Initial Essure® Procedure:	98
	2. Post Essure® Procedure Condition and Treatment:	98
Q.	TRESSA SHIELDS	101
	1. Initial Essure® Procedure:	101
	2. Post Essure® Procedure Condition and Treatment:	101
R.	MAIDA URIBE	102
	1. Initial Essure® Procedure:	103
	2. Post Essure® Procedure Condition and Treatment:	103

S.	JOY ANNA EDGE	105
	1. Initial Essure® Procedure:	105
	2. Post Essure® Procedure Condition and Treatment:	105
T.	AMY M. OLSON	107
	1. Initial Essure® Procedure:	107
	2. Post Essure® Procedure Condition and Treatment:	107
U.	RACHAEL JOHNSON	108
	1. Initial Essure® Procedure:	109
	2. Post Essure® Procedure Condition and Treatment:	109
V.	BETTY KILLY	110
	1. Initial Essure® Procedure:	110
	2. Post Essure® Procedure Condition and Treatment:	111
W.	Amber Riggs (Stewart)	111
	1. Initial Essure® Procedure:	112
	2. Post Essure® Procedure Condition and Treatment:	112
X.	CONNIE HARRIS	114
	1. Initial Essure® Procedure:	114
	2. Post Essure® Procedure Condition and Treatment:	114
Y.	MICHELLE L. THOMAS	115
	1. Initial Essure® Procedure:	115
	2. Post Essure® Procedure Condition and Treatment:	116
Z.	MICHELLE D. SEIBER	116
	1. Initial Essure® Procedure:	116
	2. Post Essure® Procedure Condition and Treatment:	116
AA.	JENNIFER C. CARLSON	117
	1. Initial Essure® Procedure:	117
	2. Post Essure® Procedure Condition and Treatment:	117
BB.	LAKESHIA N. EDWARDS	118
	1. Initial Essure® Procedure:	118
	2. Post Essure® Procedure Condition and Treatment:	119
CC.	TIESHA M. MOSLEY	119
	1. Initial Essure® Procedure:	119
	2. Post Essure® Procedure Condition and Treatment:	119

DD.	KRISTY R. SILVERS	120
	1. Initial Essure® Procedure:	120
	2. Post Essure® Procedure Condition and Treatment:	120
EE.	MICHELLE L. BRANHAM	121
	1. Initial Essure® Procedure:	121
	2. Post Essure® Procedure Condition and Treatment:	121
FF.	ELIZABETH A. CLAAR	122
	1. Initial Essure® Procedure:	122
	2. Post Essure® Procedure Condition and Treatment:	122
GG.	TASCHA FARNSWORTH	123
	1. Initial Essure® Procedure:	123
	2. Post Essure® Procedure Condition and Treatment:	123
HH.	TAMIKA K. JACKSON	124
	1. Initial Essure® Procedure:	124
	2. Post Essure® Procedure Condition and Treatment:	125
II.	JAMIE D. KAMBARIAN	125
	1. Initial Essure® Procedure:	125
	2. Post Essure® Procedure Condition and Treatment:	125
JJ.	SHAMICA L. JONES	126
	1. Initial Essure® Procedure:	126
	2. Post Essure® Procedure Condition and Treatment:	127
KK.	SHEENA MACKEY	127
	1. Initial Essure® Procedure:	127
	2. Post Essure® Procedure Condition and Treatment:	128
LL.	MARIA D. LOPEZ	128
	1. Initial Essure® Procedure:	129
	2. Post Essure® Procedure Condition and Treatment:	129
MM.	BRITTANY D. VEIT	129
	1. Initial Essure® Procedure:	130
	2. Post Essure® Procedure Condition and Treatment:	130
NN.	JODI L. WHITE	131
	1. Initial Essure® Procedure:	131
	2. Post Essure® Procedure Condition and Treatment:	131

OO.	AMBER ESPINOZA	132
	1. Initial Essure® Procedure:	132
	2. Post Essure® Procedure Condition and Treatment:	132
PP.	SHERRI HELMS	133
	1. Initial Essure® Procedure:	133
	2. Post Essure® Procedure Condition and Treatment:	133
QQ.	SARAH WALKER	134
	1. Initial Essure® Procedure:	134
	2. Post Essure® Procedure Condition and Treatment:	135
RR.	RACHEL SIMPSON	135
	1. Initial Essure® Procedure:	135
	2. Post Essure® Procedure Condition and Treatment:	136
SS.	DONNA BAEZA	137
	1. Initial Essure® Procedure:	137
	2. Post Essure® Procedure Condition and Treatment:	138
TT.	CHRISTINE SCHMIDT	139
	1. Initial Essure® Procedure:	139
	2. Post Essure® Procedure Condition and Treatment:	139
UU.	AMANDA SULLIVAN	141
	1. Initial Essure® Procedure:	142
	2. Post Essure® Procedure Condition and Treatment:	142
VV.	TABITHA ROSS	143
	1. Initial Essure® Procedure:	143
	2. Post Essure® Procedure Condition and Treatment:	143
WW.	BOBBY HERNANDEZ	144
	1. Initial Essure® Procedure:	144
	2. Post Essure® Procedure Condition and Treatment:	144
XX.	SHABRETA TERRELL	145
	1. Initial Essure® Procedure:	145
	2. Post Essure® Procedure Condition and Treatment:	146
YY.	NANCY RIVERA	146
	1. Initial Essure® Procedure:	147
	2. Post Essure® Procedure Condition and Treatment:	147

ZZ.	DARRIELL CLEMENTS	148
1.	Initial Essure® Procedure:.....	148
2.	Post Essure® Procedure Condition and Treatment:	148
AAA.	AMY RUTAN	149
1.	Initial Essure® Procedure:.....	150
2.	Post Essure® Procedure Condition and Treatment:	150
BBB.	LINDA SANTE.....	151
1.	Initial Essure® Procedure:.....	151
2.	Post Essure® Procedure Condition and Treatment:	151
VIII.	AGENCY, ALTER-EGO, JOINT VENTURE, AND CONSPIRACY	152
IX.	PLAINTIFFS ARE ENTITLED TO PUNITIVE DAMAGES	154
X.	CLAIMS FOR RELIEF	154
	FIRST CAUSE OF ACTION – Negligence: Failure to Warn	155
A.	CONCEPTUS AND BAYER HAD A DUTY TO REPORT ADVERSE EVENTS TO THE FDA UNDER FEDERAL LAW.	155
1.	Conceptus and Bayer Had a Federal Duty to Report AEs Under the “Conditions for Approval” of Essure®’s PMA.	156
2.	Conceptus and Bayer had a Duty to Report Adverse Events Under 21 C.F.R. § 803.50, § 814.82.	157
3.	Conceptus and Bayer had a Federal Duty to Report New Clinical Investigations and/or Scientific Studies under 21 C.F.R. § 814.84(b)(2).	159
4.	Conceptus and Bayer had Continuing Duties Under 21 C.F.R. §§ 820.198, 820.300, 820.700 & 820.100 to Discover, Investigate and Respond to Adverse Events.	159
5.	Conceptus and Bayer had a Federal Duty to Modify Essure®’s Labeling under 21 C.F.R. § 803.39(a).	160
6.	Conceptus and Bayer Chose Not to Submit a “CBE” Supplement under 21 C.F.R. § 803.39(d).	161
A.	CONCEPTUS AND BAYER HAD A DUTY TO REPORT ADVERSE EVENTS TO THE FDA UNDER PENNSYLVANIA LAW AND A DUTY TO MODIFY THE LABELING BASED ON PENNSYLVANIA LAW TO ADEQUATELY WARN PHYSICIANS AND THEIR PATIENTS.	163
B.	CONCEPTUS’ AND BAYER’S DUTY TO WARN UNDER PENNSYLVANIA LAW IS NOT DIFFERENT FROM OR IN ADDITION TO FEDERAL REQUIREMENTS.	164

C.	THERE IS A CAUSAL AND FACTUAL NEXUS BETWEEN PLAINTIFFS' INJURIES AND THE BAYER DEFENDANTS' BREACH OF THEIR STATE LAW DUTIES, AND IDENTICAL FEDERAL REQUIREMENTS.....	167
1.	Had Bayer and Conceptus Reported Adverse Events Earlier, the FDA Would Have Moved to Strengthen the Essure® Labeling Much Earlier, Prior to Plaintiffs' Implantations.	168
2.	Had Bayer and Conceptus Investigated and Reported Adverse Events Earlier, the Information in those AEs Would Have Been Available to the Medical Community as a Whole.....	169
3.	Had Bayer and Conceptus Modified the Essure® Labeling as Required under State and Federal Law, Information Regarding the True Risks, Harms and Benefits of Essure® Would Have Been Available Much Earlier.....	171
4.	Had Bayer and Conceptus Conformed to their Identical State and Federal Duties, Plaintiffs' Specific Injuries Would Not Have Occurred.....	171
D.	CONCEPTUS AND BAYER FAILED TO ACCURATELY REPORT ADVERSE EVENTS FROM THE CLINICAL TRIALS.....	173
E.	TO THE EXTENT THE ESSURE® WARNING WAS ADEQUATE, IT WAS NULLIFIED BY DEFENDANTS' CONDUCT.	174
F.	ESSURE® IS AN "ADULTERATED" AND "MISBRANDED" DEVICE AND IS THEREFORE EXTRA-REGULATORY.	175
	SECOND CAUSE OF ACTION Fraudulent Misrepresentation / Fraud in the Inducement Restat. 2d of Torts § 525.	178
A.	CONCEPTUS AND BAYER HAD AFFIRMATIVE AND CONTINUING FEDERAL DUTIES TO NOT MAKE FRAUDULENT MISREPRESENTATIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE®.....	178
B.	CONCEPTUS AND BAYER HAD STATE DUTIES TO NOT MAKE FRAUDULENT MISREPRESENTATIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE®.....	179
C.	CONCEPTUS' AND BAYER'S DUTY TO NOT MAKE FRAUDULENT MISREPRESENTATIONS UNDER PENNSYLVANIA LAW IS NOT DIFFERENT FROM OR IN ADDITION TO FEDERAL REQUIREMENTS.	180
D.	THERE IS A CAUSAL AND FACTUAL NEXUS BETWEEN PLAINTIFFS' INJURIES AND DEFENDANTS' BREACH OF ITS STATE LAW DUTIES, AND IDENTICAL FEDERAL REQUIREMENTS... ..	181
1.	Conceptus and Bayer Intentionally Misrepresented the Health and Safety Information Associated with Essure®.....	181
2.	Conceptus and Bayer Made Intentional Misrepresentations Regarding the Safety and Efficacy of Essure® Through Marketing.....	186

3. Conceptus and Bayer Intentionally Misrepresented the Comparative Risks and Benefits of Essure® to Alternative Methods of Permanent Sterilization.....	190
4. As a Direct, Proximate and Causal Result of Conceptus' and Bayer's Fraudulent Misrepresentations, Plaintiffs Sustained Substantial Injuries.....	192
THIRD CAUSE OF ACTION Fraudulent Concealment Fraudulent Omissions: Restat. 2d of Torts § 551.....	
A. CONCEPTUS AND BAYER HAD AFFIRMATIVE AND CONTINUING FEDERAL DUTIES TO NOT MAKE FRAUDULENT CONCEALMENTS AND/OR OMISSIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE®.....	196
B. CONCEPTUS AND BAYER HAD STATE DUTIES TO NOT MAKE FRAUDULENT CONCEALMENTS AND/OR OMISSIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE®.....	197
C. CONCEPTUS' AND BAYER'S DUTY TO NOT MAKE FRAUDULENT CONCEALMENTS AND/OR OMISSIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE® UNDER PENNSYLVANIA LAW IS NOT DIFFERENT FROM OR IN ADDITION TO FEDERAL REQUIREMENTS.	198
D. THERE IS A CAUSAL AND FACTUAL NEXUS BETWEEN PLAINTIFFS' INJURIES AND DEFENDANTS' BREACH OF ITS STATE LAW DUTIES, AND IDENTICAL FEDERAL REQUIREMENTS... ..	199
1. Conceptus and Bayer Intentionally Concealed and/or Omitted Material Health and Safety Information Associated with Essure®.	199
2. Conceptus and Bayer Fraudulently Concealed and/or Omitted the Risks of Essure® as Compared to Alternative Methods of Permanent Sterilization.....	202
3. As a Direct, Proximate and Causal Result of Conceptus' and Bayer's Fraudulent Concealments and/or Omissions, Plaintiffs Sustained Substantial Injuries.....	204
FOURTH CAUSE OF ACTION Negligent Misrepresentation Restat. 2d of Torts, § 552	
A. CONCEPTUS AND BAYER HAD AFFIRMATIVE AND CONTINUING FEDERAL DUTIES TO NOT MAKE MISREPRESENTATIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE®.....	206
B. CONCEPTUS AND BAYER HAD STATE DUTIES TO NOT MAKE MISREPRESENTATIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE®.....	207

C.	CONCEPTUS' AND BAYER'S DUTY TO NOT TO MAKE NEGLIGENT MISREPRESENTATIONS UNDER PENNSYLVANIA LAW IS NOT DIFFERENT FROM OR IN ADDITION TO FEDERAL REQUIREMENTS.....	208
D.	THERE IS A CAUSAL AND FACTUAL NEXUS BETWEEN PLAINTIFFS' INJURIES AND DEFENDANTS' BREACH OF THEIR STATE LAW DUTIES AND IDENTICAL FEDERAL REQUIREMENTS....	208
1.	Conceptus and Bayer Negligently Misrepresented the Health and Safety Information Associated with Essure®	209
2.	Conceptus and Bayer Made Negligent Misrepresentations Regarding the Safety and Efficacy of Essure® Through Marketing.....	210
3.	Conceptus and Bayer Negligently Misrepresented the Comparative Risks and Benefits of Essure® to Alternative Methods of Permanent Sterilization.	210
4.	As a Direct, Proximate and Causal Result of Conceptus' and Bayer's Negligent Misrepresentations, Plaintiffs Sustained Substantial Injuries.	210
	FIFTH CAUSE OF ACTION Negligent Training	213
	SIXTH CAUSE OF ACTION Negligent Failure to Test Restat. 2d of Torts § 398	217
	SEVENTH CAUSE OF ACTION Breach of Express Warranty 13 Pa. Cons. Stat. § 2313	220
	EIGHTH CAUSE OF ACTION Strict Liability Restat. 2d of Torts § 402A	223
A.	PLAINTIFFS HAVE A CAUSE OF ACTION UNDER <i>TINCHER V.</i> <i>OMEGA FLEX</i> AND THE RESTATEMENT (SECOND) OF TORTS § 402A.....	223
1.	Conceptus and Bayer Failed to Comply with the Following Federal Requirements Regarding Essure®	225
2.	Conceptus and Bayer Failed to Comply with FDA Approval of Essure®, Resulting in a "Manufacturing Defect" of the Device.	227
B.	THERE IS A CAUSAL AND FACTUAL NEXUS BETWEEN PLAINTIFFS' INJURIES AND DEFENDANTS' BREACH OF ITS STATE LAW DUTIES AND IDENTICAL FEDERAL REQUIREMENTS....	230
	NINTH CAUSE OF ACTION Violation of Pennsylvania Unfair Trade Practices and Consumer Protection Law (UTCPL) 73 P.S. § 201-1 et seq.	231

IN THE COURT OF COMMON PLEAS OF ALLEGHENY COUNTY, PENNSYLVANIA

: CIVIL DIVISION

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: G.D. No. _____

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: Code: 004

**KEISHA WISE, AMY DANISAVICH, MARIE
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URIBE, CRYSTAL ADAMS, JOYANNA
EDGE, AMY OLSON, RACHAEL JOHNSON,
BETTY KILLY, AMBER RIGGS, CONNIE
HARRIS, MICHELLE THOMAS, MICHELLE
SIEBER, JENNIFER CARLSON, LAKESHIA
EDWARDS, TIESHA MOSLEY, KRISTY
SILVERS, MICHELLE BRANHAM,
ELIZABETH CLAAR, TASCHA
FARNSWORTH, TAMIKA JACKSON, JAMIE
KAMBARIAN, SHAMICA JONES, SHEENA
MACKEY, MARIA LOPEZ, BRITTANY
VEIT, JODI WHITE, AMBER ESPINOZA,
AMY RUTAN, DONNA BAEZA, RACHEL
SIMPSON, AMANDA SULLIVAN, DARRIELL
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LILYBETT MARTIR, SHERRI HELMS,
RAEMARIE COLEMAN, TARA
DAUGHERTY, CHELSEA DEYARMIN,
JACKIE MEYER, BOBBY HERNANDEZ,
TABITHA ROSS, SARAH WALKER, LINDA
SANTE**

Plaintiffs,

v.

**BAYER U.S. LLC/
Bayer U.S. LLC;**

BAYER HEALTHCARE LLC;

Defendants.

COMPLAINT IN A CIVIL ACTION

COME NOW Plaintiffs, by and through their undersigned counsel, and state as their Complaint for Damages against BAYER U.S. LLC, and BAYER HEALTHCARE LLC (collectively herein referred to as “Bayer” or “Conceptus” or the “Bayer Defendants”) for personal injuries suffered as a result of being implanted with the defective and unreasonably dangerous product Essure®.

I. INTRODUCTION

1. This is an action for the serious and permanent injuries incurred by the Plaintiffs resulting from the promotion, sale, and distribution of an unreasonably dangerous and defective medical device product known as Essure®.

2. Conceptus Inc. ("Conceptus") came up with the idea for the Essure® device in 1998.

3. At that time, Conceptus was in hundreds of millions of dollars of debt.

4. The marketplace for permanent birth control was and is enormous. In 2007, Conceptus estimated that 700,000 American women undergo incisional tubal ligation each year. The market presented a huge business opportunity to Conceptus.

5. The Essure® system consists of two metal coils that are implanted into a woman's fallopian tubes that expand and are intended to elicit tissue growth that causes blockage of the tubes and thus prevents conception.

6. The device was intended to be promoted as a simple solution to permanent birth control needs, and as safer than all other permanent birth control options.

7. By the time the FDA approved Essure® for sale in 2002, it was Conceptus' only commercial product.

8. Conceptus relied entirely on the success of Essure® to solve its massive debt problems and achieve profitability.

9. Essure[®] was a unique contraceptive device, and the first of its kind on the market.

10. As such, Conceptus knew that physicians and patients needed to trust the safety of the device for it to be accepted in the marketplace and compete with other, more established and traditional alternative methods of permanent birth control.

11. Conceptus knew that any apprehensions about the safety of the Essure[®] device on the part of physicians or patients could devastate sales and lead to the complete failure of the company.

12. To promote the perceived safety of the device and gain market acceptance, Conceptus devised and implemented a scheme to defraud physicians and patients, by means of false and fraudulent pretenses, representations and concealment of material facts.

13. After Essure[®] came onto the market, thousands of Essure[®] patients complained of adverse events directly to Conceptus.

14. Conceptus knew that if those complaints made it to the FDA and became public knowledge, it would inevitably result in changes to the Essure[®] label, its risk/benefit profile, related physician advice, and patients' decisions.

15. In short, Conceptus knew that if the true safety risks and consequences were known to the public, sales of the device would plummet.

16. As a result, Conceptus made a decision to hide these safety risks and consequences from the FDA and the public.

17. Conceptus was obligated under federal and parallel state law to report the patients' complaints to the FDA.

18. Conceptus withheld the vast majority of those complaints.

19. At the same time, Conceptus conducted enormous and aggressive marketing campaigns that disseminated what they knew to be false and misleading statements pertaining to the convenience, safety and efficacy of the device.

20. Conceptus engaged in substantial, widespread and systemic false, misleading and illegal promotional activities to encourage physicians and patients to use the Essure[®] device.

21. While Conceptus engaged in substantial, widespread and systemic false, misleading and illegal promotional activities, it violated its duty owed to the physicians and patients, in concealing and failing to warn the physicians and patients of the known serious increased risks and complications stemming therefrom.

22. Conceptus knew that the withholding of safety information and adverse events, as well as the dissemination of false and misleading statements pertaining to the Essure[®] device was illegal.

23. In fact, the FDA cited Conceptus several times for withholding safety information.

24. Conceptus knew that manipulating the public's knowledge of safety risks associated with Essure[®] exposed patients to serious dangers and greatly increased adverse risks.

25. Despite knowing of these dangers and the illegality of their behavior, Conceptus continued to carry out its false and unlawful marketing and promotional scheme, with an intent to deceive.

26. These illegal efforts proved to be highly effective, leading to hundreds of millions of dollars in revenue for Conceptus, and an eventual buyout of the company by Bayer for approximately \$1.1 billion in 2013.

27. Bayer continued illegally hiding the true safety risks of Essure[®].

28. Those same tactics could not continue working for Bayer.

29. In 2013, the FDA began promoting the use of the MedWatcher app, a system that allowed patients with complaints to report their problems directly to the FDA itself, as opposed to the manufacturer.

30. By that time, thousands of women adversely affected by the Essure[®] device had formed a support group named "Essure Problems" on Facebook, a digital social network.

31. The group currently consists of over 36,000 members.

32. Conceptus and Bayer had been able to effectively silence their voices and conceal their complaints for years because the companies controlled what information did and did not make it to the FDA.

33. However, through the use of the MedWatcher app, in the fall of 2013 these women began to stand up to Bayer and report their problems directly to the FDA.

34. At that point, Bayer knew Essure[®] was wreaking havoc on the lives of thousands of women.

35. Bayer could have chosen to acknowledge the true weight of all this safety information and stopped promoting the device.

36. But with over a billion dollars invested in Essure[®], Bayer chose to protect its investment and continue promoting the false impression that the device was safe.

37. Bayer knew that they could no longer hide complaints made through MedWatcher, because those reports were made directly to the FDA.

38. So, Bayer began to employ new tactics to conceal and downplay the true safety risks of Essure[®].

39. Bayer carefully manipulated its reports to the FDA and presented false and misleading information.

40. Bayer did this in an effort to maintain the impression that the Essure[®] device had a positive risk/benefit profile and to guard sales.

41. Women affected by Essure[®] and certain members of the "Essure Problems" group, however, would not let Bayer continue to mislead the FDA and more women.

42. They demanded that the FDA take meaningful action to investigate and evaluate the growing scientific knowledge concerning Essure[®].

43. At their insistence, in September of 2015 the FDA convened a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee to hear concerns from experts and patients, and plan recommendations for the Essure[®] device.

44. At the hearing, experts funded by the "Essure Problems" group testified as to the many safety problems they had begun to observe with the device.

45. Shortly after the hearing, researchers from Cornell University published a study in the British Medical Journal with devastating conclusions about the comparative safety profile of Essure[®].

46. The study compared thousands of women from New York State who had undergone either a traditional tubal ligation or received the Essure[®] implant and concluded that women receiving Essure[®] were ten times more likely to require a corrective reoperation.

47. Based on the information gathered by the FDA during the advisory process, the FDA realized that "patients are not reliably receiving and/or understanding appropriate information about the device and associated risks prior to making a sterilization decision – for Essure as well as other sterilization methods,"¹ and the FDA finally took aggressive action.

¹ See *FDA Activities: Essure*, <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm> (last updated December 28, 2017).

48. In 2016, the FDA required a detailed boxed warning for the Essure[®] device.

49. The FDA reserves boxed warnings, commonly referred to as "black box warnings," for only the most serious adverse events.

50. Boxed warnings indicate the highest level of risk.

51. The FDA also required that every potential Essure[®] patient receive and sign a detailed checklist specifically tailored to the risks associated with the device.

52. The boxed warning and patient decision checklist were approved by the FDA on November 15, 2016.²

53. In its current form, this patient decision checklist requires a patient's initials and signature six separate times.

54. The checklist specifically warns of device migration and perforation of organs, side effects that Conceptus and Bayer had been cited for hiding from the FDA and the public for years.

55. On April 9, 2018, the FDA restricted sales of the Essure[®] device to doctors and healthcare facilities who use the "Patient-Doctor Discussion Checklist – Acceptance of Risk and Informed Decision Acknowledgement." "The FDA is requiring a unique type of restriction, using its authority to restrict the sale and distribution of a device to impose additional requirements needed to provide a reasonable assurance of its safety and effectiveness."³

56. As a result, women considering the device will have the chance to be fully informed of its true risks.

² See *Premarket Approval (PMA)*, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014S046> (last updated January 22, 2018).

³ See "FDA restricts sale and distribution of Essure to protect women and to require that patients receive risk information," April 9, 2018, located at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm604098.htm>.

57. Finally, on July 20, 2018, Bayer announced its plans to halt Essure® sales in the United States, effective December 31, 2018⁴.

58. Conceptus and Bayer knowingly and purposefully concealed these risks for years.

59. Unfortunately, Plaintiffs herein were not afforded the knowledge and warnings that would have informed and protected them.

II. PARTIES

A. PLAINTIFFS.

60. Below is a list of each Plaintiff who is bringing her own case against Defendants:

61. Plaintiff, Keisha Wise, resides in Pittsburgh, Allegheny County, Pennsylvania; and she was implanted with the Essure® device during a procedure at Magee-Womens Hospital in Pittsburgh, Allegheny County, Pennsylvania.

62. Plaintiff, Amy Danisavich, resides in Cumbola, Schuylkill County, Pennsylvania; and she was implanted with the Essure® device during a procedure at The Pottsville Hospital and Warne Clinic in Pottsville, Schuylkill County, Pennsylvania.

63. Plaintiff, Jackie Meyer, resides in New Castle, Lawrence County, Pennsylvania; and she was implanted with the Essure® device at the University of Pittsburgh Medical Center – Jameson in New Castle, Lawrence County, Pennsylvania.

64. Plaintiff, Chelsea Deyarmin, resides in Altoona, Blair County, Pennsylvania; and she was implanted with the Essure® device at the University of Pittsburgh Medical Center-Altoona in Altoona, Blair County, Pennsylvania.

⁴ See, “Statement from FDA Commissioner Scott Gottlieb, M.D., on manufacturer announcement to halt Essure sales in the U.S.; agency’s continued commitment to postmarket review of Essure and keeping women informed,” July 20, 2018, located at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm614123.htm>.

65. Plaintiff, Raemarie Coleman, resides in Philadelphia, Philadelphia County, Pennsylvania; and she was implanted with the Essure[®] device at Einstein Medical Center in Philadelphia, Philadelphia County, Pennsylvania.

66. Plaintiff, Tara Daugherty, resides in Morgantown, Monongalia County, West Virginia; and she was implanted with the Essure[®] device at Uniontown Hospital in Uniontown, Fayette County, Pennsylvania.

67. Plaintiff, Crystal Adams, resides in Indianapolis, Marion County, Indiana; and she was implanted with the Essure[®] device during a procedure at Obstetrics & Gynecology of Indiana in Indianapolis, Marion County, Indiana.

68. Plaintiff, Lilybett Martir, resides in Belleville, Essex County, New Jersey; and was implanted with the Essure[®] device during a procedure at Clara Mass Medical Center in Belleville, Essex County, New Jersey.

69. Plaintiff, Marie Collins Hughes, resides in Wynne, Cross County, Arkansas; and she was implanted with Essure[®] device during a procedure at the offices of Brandy A. Davis, MD, in Forrest City, St. Francis County, Arkansas.

70. Plaintiff, Marsha Creasey, resides in Lexa, Phillips County, Arkansas; and she was implanted with Essure[®] device during a procedure at The Women's Health Clinic of Forrest City, St. Francis County, Arkansas.

71. Plaintiff, Amber Hedges, resides in Malvern, Hot Spring County, Arkansas; and she was implanted with Essure[®] device during a procedure at the National Park Medical Center in Hot Springs, Garland County, Arkansas.

72. Plaintiff, Mary Powell, resides in Emmet, Nevada County, Arkansas; and she was implanted with Essure[®] device during a procedure at Baptist Health Women's Clinic in Arkadelphia, Clark County, Arkansas.

73. Plaintiff, Katherine Lucero, resides in Denver, Denver County, Colorado; and she was implanted with Essure[®] device during a procedure at the offices of Michael L. Hall, PC, in Englewood, Arapahoe County, Colorado.

74. Plaintiff, Tynisha Ellison, resides in Washington, District of Columbia; and she was implanted with Essure[®] device during a procedure at the United Medical Center in Washington, D.C.

75. Plaintiff, Angelique Abdul-Matin, resides in Duluth, Gwinnett County, Georgia; and she was implanted with Essure[®] device during a procedure at Orlando Health Physician Associates in Edgewood, Orange County, Florida.

76. Plaintiff, Stephanie Fernandez, resides in Sanford, Seminole County, Florida; and she was implanted with Essure[®] device during a procedure at South Seminole Hospital in Longwood, Seminole County, Florida.

77. Plaintiff, Tressa Shields, resides in Lithia, Douglas County, Georgia; and she was implanted with Essure[®] device during a procedure at North Florida OB/GYN Associates, P.A., in Orange Park, Clay County, Florida.

78. Plaintiff, Maida Uribe, resides in Belvidere, Boone County, Illinois; and she was implanted with Essure[®] device during a procedure at SwedishAmerican Hospital in Rockford, Boone County, Illinois.

79. Plaintiff, Joy Anna Edge, resides in Kenyon, Goodhue County, Minnesota; and she was implanted with the Essure[®] device at the Olmsted Medical Center in Rochester, Olmsted County, Minnesota.

80. Plaintiff, Amy M. Olson, resides in Detroit Lakes, Becker County, Minnesota; and she was implanted with the Essure[®] device at Essentia Health St. Mary's – Detroit Lakes Clinic in Detroit Lakes, Becker County, Minnesota.

81. Plaintiff, Rachael Johnson, resides in St. Louis, St. Louis County, Missouri; and she was implanted with the Essure[®] device at Barnes Jewish Hospital in St. Louis, St. Louis County, Missouri.

82. Plaintiff, Betty Killy, resides in Las Vegas, Clark County, Nevada; and she was implanted with the Essure[®] device at UP-Smiley Lane Clinics in Columbia, Boone County, Missouri.

83. Plaintiff, Amber Riggs (Stewart), resides in Portsmouth, Scioto County, Ohio; and she was implanted with the Essure[®] device at Pike Community Hospital in Waverly, Pike County, Ohio.

84. Plaintiff, Connie Harris, resides in Easley, Pickens County, South Carolina; and she was implanted with the Essure[®] device at Greenville Memorial Hospital in Greenville, Greenville County, South Carolina.

85. Plaintiff, Michelle L. Thomas, resides in St. Louis, St. Louis County, Missouri; and she was implanted with the Essure[®] device at Barnes Jewish Hospital in St. Louis, St. Louis County, Missouri.

86. Plaintiff, Michelle Seiber, resides in St. Louis, St. Louis County, Missouri; and she was implanted with the Essure[®] device at Missouri Baptist Medical Center in St. Louis, St. Louis County, Missouri.

87. Plaintiff, Jennifer C. Carlson, resides in Chesapeake, Virginia; and she was implanted with the Essure[®] device at Planned Parenthood of Southeastern Virginia in Virginia Beach, Virginia.

88. Plaintiff, Lakeshia N. Edwards, resides in Little Rock, Pulaski County, Arkansas; and she was implanted with the Essure[®] device at Parkhill Clinic for Women in Fayetteville, Washington County, Arkansas.

89. Plaintiff, Tiesha M. Mosley, resides in Stafford, Fort Bend County, Texas; and she was implanted with the Essure[®] device at Memorial Hermann Sugar Land Hospital in Sugar Land, Fort Bend County, Texas.

90. Plaintiff, Kristy R. Silvers, resides in Dalton, Whitfield County, Georgia; and she was implanted with the Essure[®] device at the North Georgia Women's Center in Dalton, Whitfield County, Georgia.

91. Plaintiff, Michelle L. Branham, resides in Midlothian, Cook County, Illinois; and she was implanted with the Essure[®] device at Planned Parenthood of Illinois in Kane County, Aurora, Illinois.

92. Plaintiff, Elizabeth A. Claar, resides in West Farmington, Trumbull County, Ohio; and she was implanted with the Essure[®] device at Cortland Ob/Gyn Associates in Warren, Trumbull County, Ohio.

93. Plaintiff, Tascha Farnsworth, resides in Rancho Murieta, Sacramento County, California; and she was implanted with the Essure[®] device at Point West Medical Offices in Sacramento, Sacramento County, California.

94. Plaintiff, Tamika K. Jackson, resides in Baltimore, Baltimore County, Maryland; and she was implanted with the Essure[®] device at the University of Maryland Medical Center Women's Health in Baltimore, Baltimore County, Maryland.

95. Plaintiff, Jamie D. Kambarian, resides in Godfrey, Madison County, Illinois; and she was implanted with the Essure[®] device at West County Ob/Gyn in St. Louis, St. Louis County, Missouri.

96. Plaintiff, Shamica L. Jones, resides in Elk Grove, Sacramento County, California; and she was implanted with the Essure[®] device at Kaiser Permanente Elk Grove Medical Offices in Elk Grove, Sacramento County, California.

97. Plaintiff, Sheena Mackey, resides in Canyon Lake, Comal County, Texas; and she was implanted with the Essure[®] device New Braunfels Ob/Gyn in New Braunfels, Comal County, Texas.

98. Plaintiff, Maria D. Lopez, resides in Odessa, Ector County, Texas; and she was implanted with the Essure[®] device at Permian Women's Center in Ector County, Odessa, Texas.

99. Plaintiff, Brittany D. Veit, resides in Cross Lanes, Kanawha County, West Virginia; and she was implanted with the Essure[®] device at Thomas Memorial Hospital in Kanawha County, South Charleston, West Virginia.

100. Plaintiff, Jodi L. White, resides in San Antonio, Bexar County, Texas; and she was implanted with the Essure[®] device at Geary Community Hospital in Geary County, Junction City, Kansas.

101. Plaintiff, Amber Espinoza, resides in Glendale, Arapahoe County, Colorado; and she was implanted with the Essure[®] device at Mile High Ob-Gyn in Denver, Arapahoe County, Colorado.

102. Plaintiff, Sherri Helms, resides in Warren, Trumbull County, Ohio; and she was implanted with the Essure[®] device at Trumbull Memorial Hospital in Warren, Ohio.

103. Plaintiff, Sarah Walker, resides in Provo, Utah County, Utah; and she was implanted with the Essure[®] device at Revere Medical Center in Pleasant Grove, Utah.

104. Plaintiff, Rachel Simpson, resides in Aurora, Arapahoe County, Colorado; and she was implanted with the Essure[®] device at Pinnacle Women's Healthcare in Parker, Colorado.

105. Plaintiff, Donna Baeza, resides in Colorado Springs, El Paso County, Colorado; and she was implanted with the Essure[®] device at UCHHealth Women's Care Clinic in Colorado Springs, Colorado.

106. Plaintiff, Christine Schmidt, resides in Belleville, St. Clair County, Illinois; and she was implanted with the Essure[®] device at Memorial Hospital in Belleville, St. Clair County, Illinois.

107. Plaintiff, Amanda Sullivan, resides in Colorado Springs, El Paso County, Colorado; and she was implanted with the Essure[®] device at Women's Associates, P.C. in Colorado Springs, El Paso County, Colorado.

108. Plaintiff, Tabitha Ross, resides in Austin, Travis County, Texas; and she was implanted with the Essure[®] device at Austin Regional Clinic in Austin, Travis County, Texas.

109. Plaintiff, Bobby Hernandez, resides in Abilene, Taylor County, Texas; and she was implanted with the Essure[®] device in Abilene, Taylor County, Texas.

110. Plaintiff, Shabreta Terrell, resides in Mansfield, DeSoto Parish, Louisiana; and she was implanted with the Essure[®] device at University Health Shreveport in Shreveport, Louisiana.

111. Plaintiff, Nancy Rivera, resides in Joliet, Kendall County, Illinois; and she was implanted with the Essure[®] device at Advocate Christ Medical Center in Oak Lawn, Cook County, Illinois.

112. Plaintiff, Darriell Clements, resides in Union City, Fulton County, Georgia; and she was implanted with the Essure[®] device at Apogee Women's Health in College Park, Fulton County, Georgia.

113. Plaintiff, Amy Rutan, resides in Lathrop, San Joaquin County, California; and she was implanted with the Essure[®] device at Kaiser Permanente in Pleasanton, Alameda County, California.

114. Plaintiff, Linda Sante, resides in Pittsburgh, Allegheny County, Pennsylvania; and she was implanted with the Essure[®] device at Forbes Hospital in Monroeville, Allegheny County, Pennsylvania.

B. DEFENDANTS.

115. BAYER U.S. LLC and/or Bayer U.S. LLC has its principal place of business at 100 Bayer Road, Pittsburgh, Allegheny County, PA 15205⁵, and an address registered with the Pennsylvania Secretary of State in Dauphin County, PA. Defendant is a citizen of Pennsylvania, either through incorporation in Pennsylvania or through having its principal place of business in Pennsylvania, and is authorized to do and does business throughout the Commonwealth of Pennsylvania. Defendant, Bayer U.S. LLC and/or BAYER U.S. LLC, is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, and marketing its products, including the Essure[®] device.

116. BAYER HEALTHCARE LLC is a for-profit corporation incorporated in the state of Delaware. Defendant, Bayer HealthCare LLC, has a principal office at 100 Bayer Blvd., Whippany, NJ 07981. Defendant, Bayer HealthCare LLC, is a citizen of Delaware, Pennsylvania, New Jersey, Germany, and the Netherlands, and is authorized to do and does business throughout the Commonwealth of Pennsylvania. Defendant, Bayer HealthCare LLC, is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, and marketing its products, including the Essure[®] device.

117. Defendants, Bayer U.S. LLC and Bayer HealthCare LLC, are hereafter collectively referred to as “Bayer,” or “Defendants,” or the “Bayer Defendants.”

118. At all relevant times herein mentioned, Bayer authorized and directed and/or participated in the promotion and sale of Essure[®], when they knew, or with the exercise of reasonable care should have known, of the increased risks, hazards, and unreasonable dangerous

⁵ See January 23, 2018 FCC Filing at p. 3, available at <http://docquery.fec.gov/pdf/531/201801239090524531/201801239090524531.pdf#navpanes=0> (last visited January 29, 2018).

propensities, and thereby actively participated in the tortious conduct which resulted in the serious injuries to the Plaintiffs described herein.

119. There exists, and at all times herein mentioned, there existed, a unity of interest in ownership between the certain Defendants and other Defendants such that any individuality and separateness between them has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as any entity distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction fraud and/or would promote injustice.

120. At all times herein mentioned, the Bayer Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling the Essure[®] device, and processing, reporting, and storing adverse events related to the device. These products were for use by the Plaintiffs and Plaintiffs' physicians. As such, each of the Bayer Defendants are liable to the Plaintiffs for their damages.

121. The harm caused to Plaintiffs resulted from the conduct of one or various combinations of the Defendants, and through no fault of Plaintiffs. There may be uncertainty as to which one or which combination of Defendants caused the harm. Defendants have superior knowledge and information on the subject of which one, or which combination of, the Defendants caused Plaintiffs' injuries.

122. Thus, the burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by the Plaintiffs.

III. JURISDICTION AND VENUE

123. This Court has personal jurisdiction, pursuant to 42 Pa.C.S. § 5301 *et seq.*, over the Defendants because, at all relevant times, they have engaged in continuous and substantial business activities in the Commonwealth of Pennsylvania.

124. This court has general personal jurisdiction because the U.S. Headquarters for Bayer is located in Pittsburgh, Pennsylvania.⁶

125. As alleged in paragraph 119-20 *supra* and 1005 *et seq.*, the Bayer entities herein are unitary, so that jurisdiction over the parent would draw jurisdiction over the subsidiaries.

126. Defendants engaged in conduct in the state of Pennsylvania that was so “continuous and systematic” as to render them “at home” in the forum state, including but not limited to business, marketing, regulatory and research activities.

127. Defendant, Bayer HealthCare LLC, is a citizen of Pennsylvania.

128. Defendant BAYER U.S. LLC / Bayer U.S. LLC is a citizen of Pennsylvania, and has its principal office in Pittsburgh, Pennsylvania.

129. Furthermore, key officers and employees of the Bayer Defendants are located in Pittsburgh, Pennsylvania, including but not limited to Keith Abrams, who is a manager of Bayer U.S. LLC.⁷

- a. Helmut Hegger, President of Bayer Business and Technology Services LLC (BBTS), is located in Pittsburgh, Pennsylvania.⁸ BBTS is listed with the Pennsylvania Secretary of State as a prior name to Bayer U.S. LLC, which

⁶ See “HQ” designation at Pittsburgh, Pennsylvania location, <http://www.bayer.us/en/contact-us/> from January 28, 2018, attached hereto as Exhibit 1.

⁷ See <https://www.corporationwiki.com/Pennsylvania/Pittsburgh/keith-r-abrams-P7498713.aspx> (last visited January 29, 2018); and <https://www.americanconference.com/speakers/mr-keith-abrams/> (last visited January 29, 2018).

⁸ See <http://www.bayer.us/en/about-bayer/leadership/helmut-hegger/> (last updated August 18, 2017).

now (as of January 2017) maintains employees from multiple Bayer entities, including Defendant Bayer HealthCare LLC.

130. There is also “specific” personal jurisdiction, because Defendants used Pittsburgh, Pennsylvania to develop, create a marketing strategy for, label, and/or work on the regulatory approval for Essure[®], and all of the Plaintiffs’ claims arise out of or relate to the Defendants’ contacts with Pennsylvania.

131. For example, at all relevant times, regulatory activities such as due diligence, postmarket integration activities, and postmarket safety surveillance were conducted in Pennsylvania.

a. Pennsylvania was the site of clinical studies regarding Essure[®].

i. Pennsylvania was a site of the ESS305 Post-Approval Study, whose purpose was to document the bilateral placement of the ESS305 model. The data obtained from this study was intended to be used to update labeling and training procedures.⁹

ii. Pennsylvania was also a site for the ESS-NSPAS Study to Evaluate the Effectiveness of Essure Post-NovaSure Radiofrequency Endometrial Ablation Procedure Following a Successful Essure Confirmation Test.¹⁰

b. Ben Zhang, located in Pittsburgh, Pennsylvania, was the “Head of Business Transformation and Change Management” from 2009-2015, where he was responsible for overseeing a consultant team, team management, development and training, recruiting, and business development. He also served as “Interim

⁹ See Clinical Data Final Report: Ess305 Post-Approval Study, located at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm413805.pdf> (last visited January 29, 2018).

¹⁰ See https://clinicaltrials.gov/ct2/show/study/NCT01740687?show_locs=Y#contacts (last visited January 29, 2018).

Head of Consumer Relations” where he was responsible for “resolution of product liability, adverse event and crisis management issues.”¹¹ Additionally, Mr. Zhang was on the HealthCare Management Board, where he “[s]upported commercial due diligence and led the post-merger integration for Bayer’s \$1.1bn Conceptus acquisition.”¹²

- c. Further, Bayer HealthCare LLC, which is a citizen of Pennsylvania, is and was at all relevant times, responsible for the manufacturing of Essure®.
- d. Defendants and their agents, located in Pittsburgh, Pennsylvania, were involved with the acquisition of Conceptus.
- e. The Bayer Defendants also conducted sales and marketing activities in Pittsburgh, Pennsylvania, including but not limited to those activities conducted through sales representatives such as Matthew Hladek and Monica Anderson.
 - i. Additionally, Pennsylvania was home to Key Opinion Leaders, or “KOLs” for Bayer, including Carl R. Della Badia, D.O. of Drexel University – College of Medicine in Philadelphia, Pennsylvania. Dr. Della Badia was a 2008 member of the Speaker’s Bureau for Conceptus, Inc.¹³ Larry R. Glazerman, M.D., MBA of Mainline Health System in Wynnewood, Pennsylvania, was also a member.¹⁴ Further, Dr. John Roizin was a KOL for Bayer, and received payments for Essure®.¹⁵

¹¹ See LinkedIn page for Ben Zhang, available at <https://www.linkedin.com/in/benzhang2009/>.

¹² *Id.*

¹³ See https://www.aagl.org/files/08FinalProgram_No%20Ads.pdf (last visited January 28, 2018).

¹⁴ See <https://www.aagl.org/2012syllabus/12FinalProgram.pdf>.

¹⁵ See payments made on behalf of Bayer to Dr. Roizin at <http://doctors.healthgrove.com/l/610867/John-Roizin-in-Bethlehem-Pennsylvania#Open%20Payments&s=2GU8tV> (last visited January 29, 2018).

132. At all relevant times, the Bayer Defendants transacted, solicited, and conducted business in Pennsylvania through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in Pennsylvania, and committed torts in whole or in part against Plaintiffs in Pennsylvania including but not limited to negligent and wrongful conduct in connection with the design, development, testing, promoting, marketing, distribution, labeling and/or sale of Essure®.

133. This Court has subject matter jurisdiction over this action pursuant to 42 Pa.C.S. § 931.

134. Further, there is no federal subject matter jurisdiction because no federal question is raised, and there is no diversity jurisdiction because the Bayer Defendants are citizens of Pennsylvania.

135. Likewise, there is no federal diversity jurisdiction, because Plaintiffs, Keisha Wise, Amy Danisavich, Jackie Meyer, Chelsea Deyarmin, Raemarie Coleman, and Linda Sante and Defendants, Bayer US LLC and Bayer HealthCare LLC, are citizens of Pennsylvania. Additionally, Defendant Bayer Healthcare LLC and Plaintiff, Lilybett Martir, are citizens of New Jersey.

136. Venue is proper in this Court, pursuant to Pa. R. Civ. P. 1006 and 2179, as Pittsburgh is the location where the Bayer Defendants have their principal place of business and/or where they regularly conduct business; where Plaintiffs' causes of action arose, and/or where a transaction or occurrence took place out of which this cause of action arose.

137. The Plaintiffs herein are all properly joined in this action pursuant to Pa. R. Civ. P. 2229(a) as they assert a right to relief under the same transaction, occurrence, or series of transactions or occurrences, and a question of law or fact is common to all Defendants in the action.

IV. FACTS

A. DESCRIPTION OF ESSURE® AND HOW IT WORKS.

138. Essure® is a Class III medical device manufactured, designed, formulated, tested, packaged, labeled, produced, constructed, assembled, marketed, advertised, promoted, distributed, and sold by Bayer.¹⁶

139. In April 2002, Conceptus, the original manufacturer of Essure®, submitted its Premarket Approval Application to the United States Food and Drug Administration (“FDA”) for the Essure® system. The Essure® system was approved by the FDA on November 4, 2002. At the time of approval, Essure® was manufactured and marketed by Conceptus, Inc. (Bayer acquired Conceptus on June 5, 2013).¹⁷

140. Essure® is considered a permanent form of female birth control and therefore is not intended to be removed.¹⁸

141. The Essure® system consists of three components: (1) two micro-inserts (coils), (2) a disposable delivery system, and (3) a disposable split introducer. All components are intended for single use.

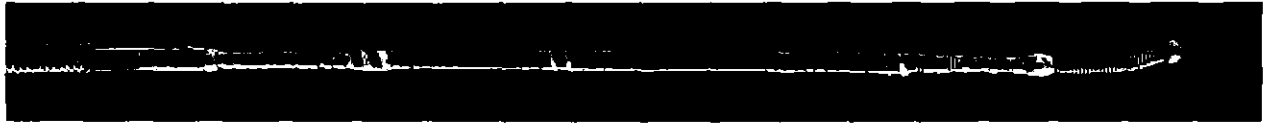
142. The Essure® micro-inserts are constructed of a stainless steel inner coil, a dynamic outer coil made from a nickel and titanium alloy, called Nitinol, and a layer of polyethylene terephthalate, or polyester fibers, wound between the inner and outer coils.¹⁹

¹⁶ See “Essure® Permanent Birth Control: Regulatory History,” available online at: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452270.htm> (last updated December 28, 2017).

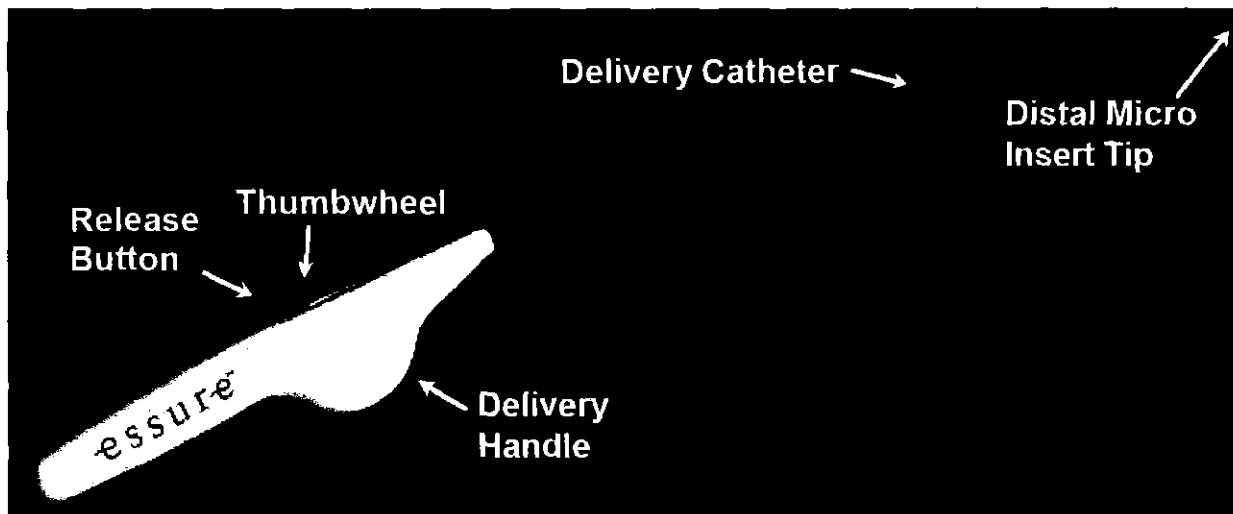
¹⁷ *Id.*

¹⁸ See “Essure® Permanent Birth Control,” available online at: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/default.htm> (last updated August 23, 2017).

¹⁹ Essure® Micro-Insert shown below in its “Wound-Down Configuration”, attached to release catheter.



143. Essure[®]'s disposable delivery system consists of a single handle containing a delivery wire, release catheter, and delivery catheter. The micro-inserts are attached to the delivery wire. The delivery handle controls the device, delivery, and release. Physicians are allowed to visualize this complicated process through the hysteroscopic (camera) equipment provided by Bayer.²⁰



144. During the Essure[®] system implantation procedure, a physician inserts the Essure[®] micro-inserts through the vagina and cervix and into the fallopian tubes via Defendants' disposable delivery system using a hysteroscope for guidance.

145. Once the physician has properly positioned the delivery system in the fallopian tube, the physician releases the micro-insert. When released, the micro-insert automatically expands to the contours of the fallopian tube to anchor into the fallopian tube permanently.²¹

²⁰ Essure[®] Delivery System is pictured below.

²¹ Essure[®] Micro-insert shown below in its "Expanded Configuration."

146. After implantation and over a 3-month period, the polyethylene terephthalate (PET) fibers on the micro-inserts are supposed to elicit tissue growth around the coils, which causes bilateral occlusion (blockage) of the fallopian tubes. The build-up of tissue creates a barrier that keeps sperm from reaching the eggs, thus preventing conception.²² During the 3-month time period, the woman must use another form of birth control while tissue in-growth occurs.

147. Three (3) months following the procedure, the patient is to receive a “Confirmation Test” to determine whether the Essure[®] micro-inserts have created a complete occlusion in each fallopian tube. The Confirmation Test used is a hysterosalpingogram (“HSG”), which is performed by slowly adding contrast dye into the uterus until the uterine cornua are distended. Bayer has admitted that the HSG test is “often painful” and “is also known to be highly inaccurate, with false-positive results in as many as 40% of HSG-diagnosed cases of proximal tubal occlusion (“PTO”). Various factors are believed to be responsible for these false indications of tubal occlusion, including tubal spasm (a natural function of the tubes) and a build-up in the tube of natural cellular debris and mucous.”

B. MEDICAL DEVICE REGULATORY FRAMEWORK.

148. To understand the full scope of the allegations contained in this Complaint, a brief general background regarding the applicable FDCA provisions is warranted, as well as an application of those laws to the present case.²³

²² See “Essure Permanent Birth Control,” available online at:

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/default.htm> (last updated August 23, 2017).

²³ Plaintiffs are not seeking to enforce these provisions in this action. Likewise, Plaintiffs are not suing merely because the Bayer Defendants’ conduct violates these provisions. Rather Plaintiffs are alleging that the Bayer Defendants’ conduct that violates these federal regulations, as well as the PMA obtained for

149. The United States Food and Drug Administration (“FDA”) is the federal agency of the United States of America that is charged with safeguarding the health and safety of the public by enforcing the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.* (2012) (the “FDCA”).²⁴

150. In 1976, Congress enacted the Medical Device Amendments of 1976 (“MDA”) to extend the coverage of the FDCA to medical devices. The MDA was passed to protect patients with the idea that medical devices should be subjected to a rigorous approval process for specific indications before medical device manufacturers are allowed to market them. Therefore, the FDA has authority over drugs and medical devices under the FDCA and the MDA.

151. The MDA established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective according to user risk. Class I Medical Devices pose the least risk, whereas Class III Medical Devices pose the greatest risk to the users.²⁵

152. Class I Medical Devices are subject to “general controls” such as labeling requirements.²⁶ Class II Medical Devices are subject not only to “general controls,” but also to “special controls” such as “performance standards, post market surveillance, and patient registries.”²⁷ If a device cannot be determined to provide a reasonable assurance of safety and effectiveness under Class I or II controls and is either marketed as a life supporting device or may cause an unreasonable risk of illness or injury, then it rises to the level of a Class III Medical Device.²⁸

Essure®, also violates parallel state laws.

²⁴ The ultimate responsibility for the safety of a medical device rests with the manufacturer.

²⁵ 21 U.S.C. § 360c(a)(1) (2012).

²⁶ 21 U.S.C. § 360c(a)(1)(A) (2012).

²⁷ 21 U.S.C. § 360c(a)(1)(B) (2012).

²⁸ 21 U.S.C. § 360c(a)(1)(C) (2012).

153. Class III Medical Devices are the most regulated. The MDA defines a Class III Medical Device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury.²⁹ Class III Medical Devices pose the greatest risk of death or complications and include most implantable surgical devices.

154. Essure[®] is a Class III device and received FDA's most stringent review prior to marketing, using the Premarket Approval (PMA) process.³⁰

1. Class III Medical Device Pre-Market Approval Requirements.

155. Before a company can market a Class III Medical Device, the company is required to submit a premarket application to the FDA supported by data that provides the FDA with a reasonable assurance that the medical device is safe and effective for its intended use.³¹ In order to show safety and effectiveness, the applicant is required to submit evidence to the FDA, typically in the form of clinical trial results.

156. A PMA application must contain certain information, which is critical to the FDA's evaluation of the safety and efficacy of the medical device at issue.

157. Once the FDA has approved a medical device through the PMA application process (such as Essure[®]) the manufacturer/applicant is required to comply with the standards and conditions set forth in the PMA approval letter.³²

158. A Class III device that fails to meet the PMA requirements after marketing is considered to be adulterated under § 501(f) of the Federal Food, Drug and Cosmetic Act ("FDCA") and cannot continue to be marketed.

²⁹ *Id.*

³⁰ See "Essure Permanent Birth Control: Regulatory History," available online at: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452270.htm> (last updated December 28, 2017).

³¹ 21 U.S.C. § 360e(a)(2), § 360e(d)(1)(B)(iii), §360e(d)(2)(A) (2012).

³² 21 C.F.R. § 814.80 (2012).

159. Essure®'s PMA was accompanied by an attachment setting forth the general "Conditions of Approval." Some of the notable conditions made available to the public via the FDA's website required Defendant to:

- A) Conduct two Post-Approval Studies to: (1) gather five-year follow up information on the participants in the two premarket clinical trial patient cohorts (Phase 2 trial and Pivotal Trial) and (2) evaluate bilateral placement rate for newly trained physicians.³³
- B) Warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.³⁴
- C) Submit a PMA supplement when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.³⁵
- D) Submit post-approval reports required under 21 C.F.R. § 814.84 at intervals of 1 year from the date of approval of the original PMA, which shall include: (1) a bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant: (i) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and (ii) reports in the scientific literature concerning the device.³⁶
- E) Submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" within 10 days after the applicant receives or has knowledge of information concerning, in part: (1) any adverse reaction side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and: (i) has not been addressed by the device's labeling; or (ii) has been addressed by the device's labeling but is occurring with unexpected severity or frequency; (2) any significant chemical, physical or other change or deterioration in the device, or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not

³³ See "Essure Permanent Birth Control: Regulatory History," available online at: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452270.htm> (last updated December 28, 2017).

³⁴ See http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014a.pdf (The FDA specifically states that it does not evaluate information related to contract liability warranties).

³⁵ See *id.*

³⁶ *Id.*

correctable by adjustments or other maintenance procedures described in the approved labeling.³⁷

- F) Report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer: (1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.³⁸

160. The FDA made clear in the PMA order that “[f]ailure to comply with the conditions of approval invalidates this approval order and commercial distribution of a device that is not in compliance with these conditions is a violation of the act.”³⁹

2. General Reporting Duties to the FDA are Required After the PMA Process.

161. A medical device manufacturer's obligations do not end with the FDA's Premarket Approval ("PMA") process.

162. Under federal law, a medical device manufacturer has a continuing duty to monitor its product after premarket approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product.⁴⁰

163. Accurate reporting of adverse events is essential, as it serves to notify the public that a potential problem with the device exists, and can prompt an informed person or organization to develop a solution. The FDA and others, including the public, rely upon accurate and timely reporting of adverse events. Post-market surveillance by the FDA is hampered when mandatory reporting terminology is not clear, accurate, and consistent.

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ 21 C.F.R. § 803.50(a) (2012); 21 U.S.C. § 360i(a) (2012).

164. Manufacturers are required to report to the FDA “no later than 30 calendar days after the day: the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device” marketed by the manufacturer:

- A) may have caused or contributed to death or serious injury; or
- B) has malfunctioned in a manner that would likely “cause or contribute to a death or serious injury” if it recurred.⁴¹

165. “Becomes aware” means that an employee of the entity required to report has acquired information that reasonably suggests a reportable adverse event has occurred.⁴² A manufacturer is considered to have become aware of an event when any of its employees becomes aware of a reportable event that is required to be reported within 30 calendar days.⁴³ A manufacturer is also considered to have become aware of an event when any of its employees with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable Medical Device Report (“MDR”) event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.⁴⁴

166. “Serious injury” is defined as an injury or illness that: (1) is life-threatening, (2) results in permanent impairment of a body function or permanent damage to a body structure, or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.⁴⁵

⁴¹ 21 C.F.R. § 803.50(a); *see also* 21 U.S.C. § 360i(a) (further detailing the post approval reporting requirements applicable to device manufacturers).

⁴² *See* 21 C.F.R. § 803.3(b) (2012).

⁴³ *Id.*

⁴⁴ *See* 21 C.F.R. § 803.3(b)(2) (2012).

⁴⁵ 21 C.F.R. § 803.3 (2012).

167. “Malfunction” is defined as a failure of a device to meet its performance specifications or otherwise to perform as intended.⁴⁶ Performance specifications include all claims made in the labeling for the device.⁴⁷ The intended performance of a device refers to the intended use for which the device is labeled or marketed.⁴⁸

168. A malfunction should be considered reportable if any one of the following is true:

- (1) the chance of a death or serious injury resulting from a recurrence of the malfunction is not remote;
- (2) the consequences of the malfunction affect the device in a catastrophic manner that may lead to a death or serious injury;
- (3) the malfunction causes the device to fail to perform its essential function and compromises the device's therapeutic, monitoring or diagnostic effectiveness which could cause or contribute to a death or serious injury, or other significant adverse device experiences. The essential function of a device refers not only to the device's labeled use, but for any use widely prescribed within the practice of medicine; or,
- (4) the malfunction involves a long-term device implant that would prevent the implant from performing its function.⁴⁹

169. Reporters do not need to assess the likelihood that a malfunction will recur. The regulation assumes that if a malfunction has occurred once, the malfunction will recur.⁵⁰

170. *“Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.”*⁵¹

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ See “Medical Device Reporting For Manufacturers,” available online at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094529.htm#al>

⁵⁰ *Id.*

⁵¹ 21 C.F.R. § 820.198(c) (2012) (Emphasis added).

171. “When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.”⁵²

172. “Any complaint that represents an event which must be reported to FDA under part 803 of the Medical Device Reporting regulations shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of: (1) [w]hether the device failed to meet specifications; (2) [w]hether the device was being used for treatment or diagnosis; and (3) [t]he relationship, if any, of the device to the reported incident or adverse event.”⁵³

173. Manufacturers, such as Defendants, may receive device-related complaints from information from many different sources, including telephone calls or other verbal communication, FAX transmissions, written correspondence, sales representative reports, service representative reports, scientific articles (literature), internal analyses, and legal documents.⁵⁴

174. Additionally, manufacturers of Class III Medical Devices are required to make periodic reports to the FDA regarding approved devices, which must include summaries of:

- A) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant; and
- B) reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant.⁵⁵

⁵² 21 C.F.R. § 820.198(b) (2012).

⁵³ 21 C.F.R. § 820.198(d) (2012).

⁵⁴ See “Draft Guidance for Industry and Food and Drug Administration Staff: Medical Device Reporting for Manufacturers” available online at: [Http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm359566.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm359566.pdf)

⁵⁵ 21 C.F.R. § 814.84(b)(2) (2012).

175. As presented below, Defendants failed to comply with several of the aforementioned conditions of their PMA Order and federal regulations governing medical device manufacturer reporting requirements.

3. A Manufacturer Must Follow Current Good Manufacturing Practices.

176. Under 21 C.F.R. § 820.1(a) of the Quality System (“QS”) Regulation for Medical Devices, current good manufacturing practice (“CGMP”) requirements are set forth in this quality system regulation. The requirements govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the FDCA.⁵⁶ This part establishes basic requirements applicable to manufacturers of finished medical devices.

177. 21 C.F.R. § 820.5 (2012) “Quality Systems”, the FDA regulations states: “Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part.”

178. 21 C.F.R. § 820.30(i) (2012): “Design controls” states: “(i) Design changes. Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.”

179. 21 C.F.R. § 820.30(g) (2012): Design validation means establishing by objective evidence that device specifications conform with user needs and intended use(s) and “shall include testing of production units under actual or simulated use conditions.”

⁵⁶ See 21 C.F.R. § 820.1(a) (2012).

180. 21 C.F.R. § 820.22 (2012): “Quality Audit” states, in part: “Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.”

181. 21 C.F.R. § 820.160(a) (2012): “Distribution” states, in part: “Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed...” In other words, a manufacturer is only permitted to distribute a medical device that is approved.

182. 21 C.F.R. § 820.170(a) (2012): “Installation” states: “Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device.”

183. 21 C.F.R. § 803 (2012), requires that manufacturers must include information that is reasonably known to the manufacturer, timely make Medical Device Reporting (“MDR”) submissions, define the procedures for implementing corrective and preventative actions, and review sampling methods for adequacy of their intended use.

184. 21 C.F.R. § 820.100 (2012) “Corrective and Preventive Action” states, in part, that Manufacturers shall: “establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

- A) analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical

methodology shall be employed where necessary to detect recurring quality problems;

- B) investigating the cause of nonconformities relating to product, processes, and the quality system;
- C) identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;
- D) verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; [and]
- E) implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems.”⁵⁷

185. “The purpose of the corrective and preventive action subsystem is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence.”⁵⁸ Implementing corrective and preventive actions “are essential in dealing effectively with product and quality problems, preventing their recurrence, and preventing or minimizing device failures.”⁵⁹

186. As presented below, Defendants failed to comply with several of the aforementioned conditions of their PMA Order and federal regulations governing medical device manufacturing processes.

4. PMA Supplements for Labeling Changes.

187. Any changes the manufacturer believes could affect the safety and effectiveness of the device must be submitted via a “PMA Supplement,” to the FDA for approval.⁶⁰

188. While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include labeling

⁵⁷ 21 C.F.R. § 820.100 (2012).

⁵⁸ See <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm170612.htm> (last updated November 25, 2014).

⁵⁹ *Id.*

⁶⁰ 21 C.F.R. § 814.39(a) (2012).

changes if they affect the safety or effectiveness of the device.⁶¹

189. Most changes to the labeling of a device after premarket approval require prior FDA approval, but a manufacturer may place into effect:

- A) “[l]abeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association;
- B) “[l]abeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device, and;
- C) “[l]abeling changes that delete misleading, false, or unsupported indications.”⁶²

190. Under those regulations, the manufacturer is required to notify the FDA of “Changes Being Effected” (“CBE”) to a device’s labeling.

5. The FDA Prohibits Misleading or False Promotion and Marketing.

191. Under the FDCA and FDA’s implementing regulations, labeling, promotional advertisements, and making claims about medical devices are deemed misleading if they fail to disclose certain information about the product’s risks.

192. Generally, to comply with the FDCA and FDA’s implementing regulations, and therefore the PMA, such promotional pieces: (a) Cannot be false or misleading in any particular;⁶³ (b) Must reveal material facts about the product being promoted, including facts about the consequences that can result from use of the product as suggested in the promotional piece.⁶⁴

193. The FDA regulates the manufacture, sale, and distribution of medical devices in the United States under the authority of the FDCA. This authority includes oversight of labeling and advertising for all medical devices.

⁶¹ *Id.*

⁶² *Id.*

⁶³ 21 U.S.C. §352(a) (2012).

⁶⁴ 21 U.S.C. § 321(n) (2012); 21 C.F.R. § 1.21(2012).

194. A medical device shall be deemed to be misbranded if its labeling is false or misleading in any particular.⁶⁵ Labeling or advertising may be considered misleading if it fails to reveal material facts about the product being promoted, including facts about the consequences that can result from use of the product as suggested in a promotional piece.⁶⁶

195. Defendant's PMA approval letter for Essure[®] specifically states that the FDA "[d]oes not evaluate information related to contract liability warranties, however [Defendant] should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws."⁶⁷

6. Violations of Federal Statutes or FDA Regulations Void the Federal Preemption Defense.

196. There is a presumption against federal preemption of state laws that operate in traditional state domains.⁶⁸ "Throughout our history, the several States have exercised their police powers to protect the health and safety of their citizens. States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons."⁶⁹

197. "Nothing in § 360k denies [the states] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."⁷⁰

198. As the Supreme Court held in *Riegel v. Medtronic, Inc.*, "State requirements are preempted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a

⁶⁵ 21 U.S.C. § 352(a) (2012).

⁶⁶ See 21 U.S.C. § 321(n) (2012).

⁶⁷ See http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014a.pdf

⁶⁸ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

⁶⁹ *Id.* at 475.

⁷⁰ *Id.* at 495.

case “parallel,” rather than add to, federal requirements.”⁷¹

199. “The idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counterintuitive.”⁷²

200. “Medical device manufacturers who subject their Class III devices to the rigorous premarket approval process are protected by federal law from civil liability so long as they comply with federal law. That protection does not apply where the patient can prove that she was hurt by the manufacturer’s violation of federal law.”⁷³

201. Claims for failure to warn are not preempted. “Failure to warn claims are neither expressly nor impliedly preempted by the MDA to the extent that this claim is premised on [the defendant manufacturer]’s violation of FDA regulations with respect to reporting [adverse outcomes] caused by the device.”⁷⁴

202. In *Stengel v. Medtronic, Inc.*, the Supreme Court issued an Order inviting the Solicitor General to submit an Amicus Brief expressing the views of the United States. According to the Solicitor General, only device-specific federal requirements have preemptive force while “by contrast FDA’s general manufacturing and labeling regulations do not have preemptive force.”⁷⁵

203. The Solicitor General stated that “federal requirement[s] are applicable to the device within the meaning of Section 360k(a)(1) only when they are applicable to the device in

⁷¹ *Riegel v. Medtronic*, 552 U.S. 312, 330 (2008) (internal citations omitted).

⁷² *Bausch v. Stryker Corp.*, 630 F.3d 546, 549-550 (7th Cir. 2010). *See also*, *Bausch* quoted with approval by the 9th Circuit in *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1232 (9th Cir. 2013) (en banc).

⁷³ *Id.* at 550 (italicized emphasis original).

⁷⁴ *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 776 (5th Cir. 2011).

⁷⁵ U.S. Amicus Br. at 9, *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1226 (9th Cir. 2013).

question and, in accordance with FDA regulations, only when they are specific counterpart regulations or specific to a particular device.”⁷⁶

204. This reasoning led the Solicitor General to the conclusion that “[i]f a state requirement were preempted absent a specific federal requirement that reflects FDA’s weighing of competing considerations on the same subject and specific to the device, the MDA would have the ironic effect of providing less public protection from unsafe and ineffective medical devices than pre-MDA law.”⁷⁷

205. In *Stengel*, and similarly in this Complaint, the alleged conduct of the petitioner was governed by general manufacturing and labeling regulations applicable to all medical devices and not the device’s pre-market approval.

206. It is the opinion of the Solicitor General that respondents’ failure to warn claims escaped express preemption because “such a claim implicates no preemptive device-specific federal requirement.”⁷⁸

207. In summary, while manufacturers who comply with federal law may be entitled to certain protections, those who violate federal law are not entitled to preemption of state laws/immunity for their tortious conduct and in fact are liable for their conduct that violates federal law.

C. CONCEPTUS DEPENDED SOLELY ON ESSURE® SALES TO FIX THEIR PROBLEMS WITH MASSIVE DEBT AND ACHIEVE PROFITABILITY.

208. Conceptus accumulated hundreds of millions of dollars in debt throughout its existence, never achieved profitability, and looked to sales of the Essure® product as the sole solution.

209. By the end of 2007, Conceptus had an accumulated deficit of \$235.2 million.

⁷⁶ *Id.* at 8-9 (internal citations omitted).

⁷⁷ *Id.* at 11 (internal citations omitted).

⁷⁸ *Id.* at 7 (internal citations omitted).

210. By the end of 2012, after all of its concerted sales efforts, Conceptus still had an accumulated deficit of \$154.9 million.⁷⁹

211. By that time, Conceptus had been in a cumulative net loss position for twenty years, since its inception.⁸⁰

212. Conceptus stated that it would remain in an accumulated deficit position unless Essure[®] sales grew large enough to offset its expenses.⁸¹

213. Beginning in 1998, Conceptus focused solely on the design, development, and clinical testing of Essure[®].

214. By 2002, Conceptus' revenue was derived almost entirely from the sale of Essure[®] to physicians.

215. By 2007, Essure[®] was Conceptus' only commercial product. Conceptus was entirely dependent on sales of the Essure[®] device to survive, as these sales accounted for all of the company's revenues.⁸²

216. That year, Conceptus stated that if the Essure[®] device did not achieve acceptance among physicians and patients, the company would fail to sustain profitability.⁸³

D. MANIPULATING SAFETY INFORMATION ALLOWED CONCEPTUS TO BECOME A VIABLE COMPANY.

217. In order to profit from Essure[®] and survive, Conceptus needed to convince physicians and women that the device was safe.

218. Because Essure[®] was a wholly unique and new form of birth control, Conceptus did not compete with other similar products for share of an existing market.

⁷⁹ See <http://www.sec.gov/Archives/edgar/data/896778/000119312513098624/d444338d10k.htm#toc>

⁸⁰ See <http://www.sec.gov/Archives/edgar/data/896778/000119312513098624/d444338d10k.htm#toc>

⁸¹ *Id.*

⁸² See http://www.sec.gov/Archives/edgar/data/896778/000110465907007326/a07-3143_18k.htm

⁸³ See [http://www.wikinvest.com/stock/Conceptus_\(CPTS\)/Filing/10-K/2008/F2331313](http://www.wikinvest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313)

219. Instead, Conceptus needed to create a new market for its product.

220. Physicians and women needed to accept the safety of Essure[®] before there could be a demand for it.

221. Therefore, apprehensions about the device's safety have always been the biggest barrier to its success.

222. In 2007, Conceptus stated that if the Essure[®] system did not achieve acceptance among physicians and patients, the company would fail to sustain profitability.⁸⁴

223. Conceptus committed all of its resources to persuading physicians and patients to accept the Essure[®] device as a safe method of birth control.

224. Throughout its entire history, Conceptus marketed Essure[®] aggressively through the use of public relations and targeted advertising in order to create acceptance of the device among general practitioners, women and the broader medical community.⁸⁵

225. In April of 2003, Conceptus introduced Essure[®] at the annual conference of the American College of Obstetricians and Gynecologists and offered two presentations, as well as a Continuing Medical Education accredited symposium with Essure[®] as the main topic.⁸⁶

226. In June of 2003, Conceptus sent direct mail to 500,000 women, not physicians, in the Atlanta and Chicago areas.

227. The direct mail campaign encouraged those women to contact Conceptus' call centers, who then referred the women to a physician offering Essure[®] in her area.⁸⁷

228. Conceptus also ran numerous regional advertisements in a variety of magazines, such as *Parents* and *Self*.⁸⁸

⁸⁴ See [http://www.wikinvest.com/stock/Conceptus_\(CPTS\)/Filing/10-K/2008/F2331313](http://www.wikinvest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313)

⁸⁵ See <http://www.sec.gov/Archives/edgar/data/896778/000089161804000719/t96941e10vk.htm>

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.*

229. Conceptus continuously fought to achieve market acceptance for Essure®.

230. In 2008, Conceptus targeted women directly again in a marketing campaign that incorporated print media, radio and television advertising. The company claimed that the campaign was meant to drive patient awareness and increase physician office utilization.⁸⁹

231. Conceptus also employed a robust sales force whose primary goals were to persuade a growing base of physicians to offer the device.⁹⁰

232. Conceptus repeatedly treated its warning label as a tool to promote market acceptance and manipulated it to achieve those goals.

233. In 2008, Conceptus stated that it intended to make labeling improvements to Essure® in order to increase the adoption of the Essure® procedure.⁹¹

234. At one point, Conceptus' CEO described certain adequate warning information as merely a barrier to more success in sales.

235. Despite mounting complaints of allergic reactions to Essure®, in 2011, Conceptus drastically altered the warning label and removed sections that encouraged women to confirm their tolerance to nickel by use of a skin test.

236. Conceptus did not change anything about the device itself or its nickel contents.

237. Afterward, the president and CEO of Conceptus stated that the label change would strengthen the company's standing in the permanent birth control market by diminishing Essure®'s biggest competitive disadvantage.

238. Conceptus then reaffirmed its ultimate goal of gaining market acceptance by stating its intentions to aggressively present the label change to the OB/GYN community. The company planned to target those physicians who were promoting other methods of birth control because of

⁸⁹ See [http://www.wikinvest.com/stock/Conceptus_\(CPTS\)/Filing/10-K/2008/F2331313](http://www.wikinvest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313)

⁹⁰ See <http://www.sec.gov/Archives/edgar/data/896778/000119312513098624/d444338d10k.htm>

⁹¹ See [http://www.wikinvest.com/stock/Conceptus_\(CPTS\)/Filing/10-K/2008/F2331313](http://www.wikinvest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313)

potential safety issues with the Essure[®] device.

E. CONCEPTUS AND BAYER CONTINUOUSLY SPREAD FALSE AND MISLEADING INFORMATION TO ALTER PERCEPTIONS OF ESSURE[®]'S SAFETY RISKS.

239. Conceptus and Bayer advertised, promoted and marketed on its websites, and in its print and/or video advertisements, brochures and fact sheets, the following representations about Essure[®]:

- A) The Essure[®] patient brochure stated that Essure[®] was the “only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials.” However, there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Between 1997 and 2005, there were 64 pregnancies reported to Defendants. Additionally, there have been 631 reports of pregnancies according to the FDA as of December 31, 2015. Furthermore, a recent study indicates that women implanted with Essure[®] have a *ten times* greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four times greater. Defendants concealed this information from Plaintiffs and Plaintiffs’ physicians, yet promoted Essure[®] as a more effective form of permanent sterilization than a tubal ligation.
- B) The Essure[®] website, print advertising, and patient brochure describes Essure[®] as “worry free,” and as a “simple procedure performed in your doctor’s office” that takes “less than 10 minutes” and “requires no downtime for recovery” and that “eliminates the risks, discomfort, and recovery time associated with surgical procedures.” However, Defendants actively concealed and failed to report complaints of perforations and pain, which occurred as a result of the Essure[®] procedure. Additionally, Essure[®] is not worry free because there is an increased risk that the Essure[®] implants will cause women serious, life-altering complications including but not limited to debilitating pain, heavy bleeding necessitating medication and/or additional surgical intervention, allergic reactions (including but not limited to rashes, itching, bloating, swelling, headaches, tooth loss, and hair loss), autoimmune disorders, dyspareunia, hysterectomy, and other complications.
- C) The Essure[®] website, print advertising, and patient brochure stated, “the Essure[®] inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they’re properly in place.” However, the micro-inserts do not necessarily remain securely in the fallopian tubes and can migrate and be

expelled by the body, as evidenced by the over 850 reports of device migration as of December 31, 2015.⁹²

- D) The Essure[®] website, print advertising, and patient brochure stated, “the Essure[®] inserts are made from the same trusted, silicone free material used in heart stents.” However, the micro-inserts are not made from the same material as heart stents which do not elicit tissue growth. The micro-inserts are made of PET fibers, which trigger inflammation and scar tissue growth. PET fibers degrade and leach carcinogens when placed in temperatures over 65 degrees, and the human body stays at about 98 degrees. As such, PET fibers are not designed or manufactured for use in human implantation. However, the PET fibers are made of the same materials as the PVT material in some vaginal meshes, which have a high rate of expulsion.
- E) The Essure[®] website, print advertising, and patient brochure stated, “Essure[®] eliminates the risks, discomfort, and recovery time associated with surgical procedures.” However, Essure[®] does not eliminate the risks, discomfort, and recovery time associated with surgical procedures (i.e. tubal ligations) because many women who undergo the Essure[®] procedure, including Plaintiffs, have never and will never fully recover from the Essure[®] implant procedure, which has caused them serious, life-altering complications including but not limited to debilitating pain, heavy bleeding necessitating medication and/or additional surgical procedures, allergic reactions (including but not limited to rashes, itching, bloating, swelling, headaches, tooth loss, and hair loss), autoimmune disorders, dyspareunia, hysterectomy, and other complications.
- F) The Essure[®] website, print advertising, and patient brochure stated, “Essure[®] is the most effective permanent birth control available, even more effective than tying your tubes or a vasectomy” or words to that effect. Yet, Defendants’ SEC Form 10-K filing shows that Defendants never did a comparison to a vasectomy or tubal ligation. Specifically, Defendants stated they “did not conduct a clinical trial to compare the Essure[®] procedure to laparoscopic tubal ligation.”⁹³

240. Plaintiffs and Plaintiffs’ physicians relied on these representations by Conceptus and Bayer in recommending and undergoing the Essure[®] procedure.

241. Conceptus and Bayer advertised, promoted and marketed on its websites, in its print and/or video advertisements, brochures, and fact sheets the following about physicians

⁹² See

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm>

⁹³ Conceptus, Inc., Annual Report (Form 10-k) (Mar. 15, 2004).

performing the Essure[®] procedure, while failing to report the actual material facts:

- A) “[p]hysicians must be signed-off to perform Essure[®] procedure.” However, Defendants failed to adequately train the implanting physician and “signed off” on the implanting physician who did not have the requisite training.
- B) “An Essure[®] trained doctor inserts spring-like coils, called micro-inserts.” However, the implanting physician who implanted the device was not adequately trained.
- C) “The Essure[®] training program is a comprehensive course designed to provide information and skills necessary to select appropriate patients, perform competent procedures and manage technical issues related to the placement of Essure[®] micro- inserts for permanent birth control.” However, Defendants failed to adequately train the implanting physician.
- D) “[i]n order to be trained in Essure[®] you must be a skilled operative hysteroscopist. You will find the procedure easier to learn if you are already proficient in operative hysteroscopy and management of the awake patient. If your skills are minimal or out of date, you should attend a hysteroscopy course before learning Essure[®].” However, Defendants “signed off” on physicians who were not skilled operative hysteroscopists, in order to monopolize and capture the market, including implanting physician.
- E) “[i]n order to be identified as a qualified Essure[®] physician, a minimum of one Essure[®] procedure must be performed every 6–8 weeks.” However, Defendants “signed off” on “Essure[®] physicians” who did not perform the procedure every 6–8 weeks.
- F) “[t]he PET fibers are what caused the tissue growth,” and Essure[®] “works with your body to create a natural barrier against pregnancy.” However, during a PMA meeting with the FDA in 2002, Defendants represented that the trauma caused by the expanding coil hitting the fallopian tubes is what causes the inflammatory response of the tissue.

242. Plaintiffs and Plaintiffs’ implanting physician relied on these representations by Conceptus and Bayer in recommending and undergoing the Essure[®] procedure.

F. CONCEPTUS AND BAYER HAVE ALWAYS KNOWN THAT ESSURE[®] IS DANGEROUS.

1. Conceptus Was Charged with Early Regulatory Violations.

243. From the beginning of the sale of the Essure[®] device, Conceptus has repeatedly been cited by regulatory authorities for continuous violations that impacted patient safety.

244. In July of 2002, the FDA conducted a Directed PMA Data Inspection/Audit of Conceptus. At the conclusion of the inspection, the FDA inspector cited Conceptus for failing to report adverse events identified by patients during unscheduled visits in the data submitted for the Essure® PMA.

245. In June and July of 2003, the FDA conducted a Post Market Approval Inspection of Conceptus. The FDA cited Conceptus for failing to adequately analyze all quality data sources to identify existing and potential causes of non-conforming product and other quality problems, and failing to follow procedures for the control of products that do not conform to specifications.

246. In June of 2008, the California Department of Public Health, Medical Device Safety Section (“CDPH”), conducted an inspection of Conceptus’ location in Mountain View, California. The CDPH issued a Notice of Violation to Conceptus for failing to obtain a valid license to manufacture medical devices and failing to maintain procedure for inventory transfer.

2. Conceptus Knew About a Myriad of Manufacturing Problems.

247. Subsequent to obtaining its PMA, Conceptus became aware of potential quality and failure modes associated with the Essure® devices. For example, Conceptus became aware that the following failures could occur with the device and lead to adverse consequences for the patient:

- A) the stainless steel used in the device could become unpassivated, which can cause the device to rust;
- B) the nitinol could have a nickel rich oxide which the body attacks;
- C) the no-lead solder could in fact have trace lead in it;
- D) the Galvanic action between the metals used to manufacture Essure®, which causes the encapsulation of the product within the fallopian tubes, could be a continuous irritant to some patients;
- E) the nitinol in the device can degrade due to High Nickel Ion release, increasing the toxicity of the product for patients;
- F) latent manufacturing defects such as cracks, scratches, and other disruption of the smooth surface of the metal coil, may have existed in the finished

product, causing excess nickel to leach into the surrounding tissues after implantation;

- G) PET fibers degrade at 65 degrees, therefore considerable degradation is expected at 98 degrees in the human body and degradation products of the PET used in the implant can be toxic to patients, inciting both chronic inflammation and possible autoimmune issues;
- H) the PET fibers result in chronic inflammation that can cause symptoms such as pain and autoimmune issues;
- I) the mucosal immune response to nickel is different than the immune response in non-mucosal areas of the body;
- J) there was an inadequate solder joint between the inner and outer coils of the micro-insert which can cause the micro-insert to fracture/break apart, and which Bayer admits is or could be a reason for device breakage, and;
- K) the central axis was not fully adhered to the spring which can cause the micro-insert to fracture/break apart, and which Bayer admits is or could be a reason for device breakage.

3. Conceptus Concealed Thousands of Migration and Perforation Reports From the FDA.

248. Conceptus knew of thousands of instances where the Essure[®] device had migrated in a woman or perforated a woman's organs, failed to report all of them, and then fought the FDA on its reporting obligations once the agency discovered the problem.

249. In the years before 2011, Conceptus had accumulated thousands of reports from women that their devices had migrated throughout their bodies or punctured one of their organs.

250. To protect the marketability of the device, Conceptus chose not to report the vast majority of them.

251. Then, in December of 2010 the FDA conducted a "for cause" inspection of Conceptus and its reporting procedures.

252. At the conclusion of the inspection, the FDA inspector cited Conceptus for four conditions which he found objectionable and/or violations of the FDCA and federal regulations.

253. Three of the four objectionable conditions pertained to Medical Device Reporting deficiencies and/or violations and included:

- A) Conceptus' failure to submit Medical Device Reporting ("MDR") determinations to the FDA within 30 days for reports of a serious injury involving the Essure® device including 2 (two) reports of bowel perforation, and 1 (one) report of pain and the Essure® device breaking into pieces immediately following implant;
- B) Conceptus' failure to submit MDR's to the FDA within 30 days for reports of a serious injury involving the Essure® device including, but not limited to 5 (five) reports of the Essure® coils perforating the fallopian tubes and penetrating the peritoneal cavity; and
- C) Conceptus' failure to include a failure mode for perforation itself and for the Essure® micro-inserts migrating into the peritoneal cavity in their latest Risk Analysis Design FMEA for Essure®, despite having documented at least 508 complaints of perforation between January 1, 2009 and December 8, 2010, and at least 177 complaints of perforation where the micro-insert was found in the peritoneal cavity between January 1, 2009 and January 4, 2011.

254. Specifically, the FDA inspector discovered that Conceptus was not reporting complaints of Essure® coils being seen inside the patients' abdominal cavity and not opening a corrective and preventive action ("CAPA") when they became aware of these complaints.

255. The FDA discovered that Conceptus submitted MDRs and reported complaints of the coils migrating into the peritoneal or abdominal cavity only if the patient was complaining of pain and a second procedure was required to remove the device.

256. Conceptus concealed such complaints if the coil was subsequently removed during a laparoscopic tubal ligation surgery that was performed due to a failure of occlusion of the fallopian tubes.

257. The FDA inspector demanded that Conceptus report these incidents because a migrated coil was inherently likely to lead to an injury. Conceptus' own complaint files contained hundreds of instances where this condition led to a serious complication.

258. Conceptus did not agree with FDA's position that physicians and women had a right to know about all dangerous events associated with the device.

259. Instead, Conceptus officials attempted to persuade the FDA inspector that they should not be forced to report such adverse events and make them publicly available.

260. Conceptus officials argued that a coil falling out of the fallopian tube was not technically a "malfunction" of the device, and therefore it did not need to be reported.

261. The FDA inspector explained that because the coil was designed to remain inside the fallopian tube, a coil that migrates out of the fallopian tube represents a situation where the Essure[®] device is not functioning as it was designed and intended.

262. There was no medical reason to withhold this information from the public. Conceptus concealed these reports specifically to mislead physicians and women about the safety of the Essure[®] device.

263. The size and scope of Conceptus' failure to report adverse events up until that time was enormous.

264. Just between January 1, 2008 and December 6, 2010, Conceptus received at least 16,581 complaints relating to Essure[®].

265. Of these 16,581 complaints, 16,399 were never reported to the FDA.

266. Conceptus had compiled a spreadsheet of 2,752 complaints about Essure[®] received from July 20, 2010 through December 10, 2010. Not a single one of these that indicated perforation of a patient's organs was reported to the FDA.

267. In fact, during that time period Conceptus reported only 182 complaints total to the FDA.⁹⁴

⁹⁴ See <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/results.cfm>

268. At the close of the inspection on January 6, 2011, the FDA inspector made it abundantly clear to Conceptus officials that an abdominally located coil was the precursor to becoming symptomatic in all cases in which an intra-abdominal coil had to be removed surgically.

269. Nonetheless, Conceptus continued to conceal complaints if a patient had a coil in her peritoneal cavity but was asymptomatic.

270. Conceptus revealed in this inspection that it had no intention of keeping physicians and women fully informed.

271. Conceptus' sole purpose was to maintain the marketability of its device by concealing as much adverse safety information related to its device as it could.

272. Conceptus' fraudulent scheme to conceal reports of device migration and perforation was undertaken in conscious disregard of the health and safety of all Essure® patients, and in violation of federal law, the PMA, and parallel state law.

273. Thousands of vulnerable and unsuspecting patients, including the Plaintiffs herein, have been seriously and/or permanently injured as a result of Conceptus' wrongful, illegal and immoral actions.

4. Conceptus Demonstrated a Continuing Pattern of Concealing Safety Complaints.

274. In 2013, several years after being cited by the FDA for withholding safety information, the FDA discovered again that Conceptus had been concealing thousands of complaints from the agency and the public.

275. Between May and June of 2013, the FDA conducted another inspection of Conceptus' Mountain View, CA facility. This inspection included an evaluation of Conceptus' complaint handling and adverse event reporting practices.

276. The FDA's review revealed 16,047 complaints Conceptus had received regarding Essure[®] between January 2011 and the date of the inspection.

277. Of these 16,047 complaints, Conceptus withheld 15,712 from the FDA, ensuring that they would not be made public.⁹⁵

278. Out of those 16,047, the FDA inspector reviewed 18 random complaints that contained the key words "peritoneal" or "abdominal" with "pain" or "pregnancy" and discovered that none of the complaints stating that one or more of the coils were imaged outside the fallopian tubes were reported to the FDA if the patient had not reported pain at last contact.

279. Conceptus did not provide an explanation as to why the patient had stopped reporting pain, such as possible removal of the device.

280. Conceptus withheld thousands of complaints of side effects from the FDA for years because it needed to protect the perception that its device was safe.

281. If Essure[®] was ever perceived as unsafe, or not as safe as alternative birth control methods, then the device would not have achieved acceptance in the marketplace and the company would fail.

5. Trends in FDA Reports Prove That Conceptus and Bayer Withheld an Enormous Amount of Safety Information.

282. Alarming trends in the FDA's database exist because Conceptus and Bayer chose not to report adverse events to the FDA as required by federal law.

283. The FDA did not receive accurate numbers of safety reports concerning Essure[®] until Conceptus and Bayer no longer controlled the information.

284. The FDA learned of an overwhelming number of Essure[®] adverse events only after women were no longer forced to report their problems directly to Conceptus or Bayer.

⁹⁵ See <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/results.cfm> (last updated December 31, 2017).

285. Between Essure[®]'s inception in 2002 and through to 2016, the FDA received approximately 14,919 medical device reports (MDRs) related to safety problems with the device.⁹⁶

286. Of those 14,919 MDRs, only 943 were made between 2002 and October 25, 2013. The FDA received the remaining reports between October 26, 2013 and December 31, 2016.⁹⁷

287. Therefore, approximately 94% of all Essure[®] related adverse events reported through the year 2015 were reported after late October 2013.

288. In 2017, the FDA received 11,854 reports.⁹⁸ In total, the FDA has received 26,773 MDRs from 2002 through 2017.

289. More than 90% of the MDRs received in 2017 mentioned issues involving potential device removal.

290. The rate at which women suffered adverse events associated with the Essure[®] device did not change. The device itself did not change. Only the reporting mechanisms changed.

291. Up until late October 2013, women adversely affected by Essure[®] had no convenient method of reporting their problems directly to the FDA. These women were thus forced to report their problems solely to Conceptus or Bayer.

292. Around that time, the FDA introduced a new method of reporting adverse events named "MedWatcher."

293. MedWatcher is an app that allows individuals to submit their reports of serious medical device problems directly to the FDA through the convenient use of their smart phone or tablet, thus disposing of the need to contact a device manufacturer first.⁹⁹

⁹⁶ See

<https://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/essurepermanentbirthcontrol/ucm452254.htm> (last updated March 7, 2018).

⁹⁷ See *id.*

⁹⁸ See *id.*

⁹⁹ See <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ucm385880.htm> (last updated December 26, 2017).

294. Authors studying Essure[®] adverse event reporting recently concluded that the ability for women to report Essure[®] related complaints via the MedWatcher app resulted in a massive increase in Essure[®] related MDRs reported to the FDA since October 26, 2013.¹⁰⁰

295. The study, entitled *Increasing Patient Engagement in Pharmacovigilance Through Online Community Outreach and Mobile Reporting Applications: An Analysis of Adverse Event Reporting for the Essure Device in the US*, examined voluntary patient adverse event reporting directly to the FDA using the FDA's new MedWatcher app.¹⁰¹

296. The study began by encouraging women in an Essure[®] support group who had been adversely affected by the device to file a report using MedWatcher.¹⁰²

297. The Essure[®] support group was a Facebook group named "Essure Problems" consisting of women who underwent the Essure[®] procedure and began experiencing severe pain and problems related to the device. Currently, the group has over 36,000 members.¹⁰³

298. In October 2013, a representative from the MedWatcher app development team joined the "Essure Problems" group to provide technical support to patients filing adverse event reports via the MedWatcher app.

299. This change in reporting mechanisms directly caused the explosion of adverse event reports that became public after October of 2013.

300. According to "Essure Problems" group administrators, many women with Essure[®] reported these same complaints directly to Conceptus for many years prior to October of 2013.

¹⁰⁰ *Id.*

¹⁰¹ See "Increasing Patient Engagement in Pharmacovigilance Through Online Community Outreach and Mobile Reporting Applications: An Analysis of Adverse Event Reporting for the Essure Device in the US" available online at: <http://link.springer.com/article/10.1007/s40290-015-0106-6/fulltext.html>.

¹⁰² *Id.*

¹⁰³ See <https://www.facebook.com/groups/Essureproblems/>.

301. Those women were never contacted for follow-up investigations and Conceptus and Bayer chose not to report the vast majority of those complaints to the FDA.

302. As a result, while Conceptus maintained growing complaint files detailing thousands of problems experienced with the device, the FDA and the public only became aware of a fraction of them.

303. Conceptus and Bayer successfully concealed thousands of reports of adverse events associated with Essure® from the FDA and the public because they controlled the information for years.

6. Bayer Misled the FDA About Rates of Essure® Breaking.

304. Despite knowing about hundreds of instances of the Essure® device breaking, Bayer has repeatedly reported to the FDA that only single cases exist.

305. Between May 29, 2014 and January 20, 2016, Bayer received at least 462 complaints that a patient's Essure® coils had broken apart.

306. When forwarding the first few complaints, Bayer notified the FDA that "single cases have been reported of Essure® breakage."

307. However, as reports of breakage continued to mount, Bayer continued to submit to the FDA that only single cases of breakage had been reported.

308. After 100 individual reports of breakage accumulated, Bayer submitted to the FDA that only single cases of breakage had been reported.

309. After 200 individual reports of breakage accumulated, Bayer submitted to the FDA that only single cases of breakage had been reported.

310. After 462 individual reports of breakage accumulated, Bayer submitted to the FDA that only single cases of breakage had been reported.

311. In fact, every single report of device fracture or breakage included a statement by Bayer to the FDA stating that “single cases have been reported of Essure® breakage.”

312. Bayer did this because it knew that the FDA would not discover the trend in the data on its own.

313. Bayer knows that multiple FDA analysts read the individual MDRs that it submits, and they do not necessarily communicate with each other or compare data.

314. Therefore, when multiple FDA analysts read separate reports that each state “single cases have been reported of Essure® breakage,” it causes each individual analyst to falsely believe that instances of device breakage are extremely rare.

315. Bayer’s MDRs regarding device breakage were inaccurate, misleading, and not in compliance with MDR reporting requirements.

316. Bayer did this to withhold knowledge from the public and to prevent the FDA from requiring it to make changes to its label concerning device breakage, a condition with potentially life-threatening consequences.

7. Now the Medical Community Is Discovering What Conceptus And Bayer Knew For Years: Essure® Is Dangerous.

a. Women with Essure® Are Ten Times More Likely to Undergo Subsequent Surgical Re-Operation than Women Who Undergo a Tubal Ligation.

317. The Essure® device leads to far more complications than alternative permanent birth control methods. It is significantly less safe than the traditional alternative method of undergoing a tubal ligation.

318. On October 13, 2015, the British Medical Journal (“BMJ”) published a study entitled *Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study*, in which Dr. Art Sedrakyan of Weill Cornell Medicine

in New York and his colleagues analyzed data from women who had received either the Essure[®] implant or undergone a traditional tubal ligation between 2005 and 2013 in New York State.¹⁰⁴

319. The data included 8,048 women who underwent the Essure[®] procedure and 44,278 women who had undergone a tubal ligation.

320. This study used data collected from the New York State Department of Health Statewide Planning and Research Cooperative System, which is a database that collects patient and treatment information for every hospital discharge, outpatient service, ambulatory surgery, and emergency department records in New York State.¹⁰⁵

321. This study is the first large comparative cohort study ever to have been conducted to compare the efficacy and safety of the implant based hysteroscopic procedure with the traditional laparoscopic procedure.¹⁰⁶ It is the largest collection of data related to Essure[®] that was not controlled by Conceptus or Bayer.

322. The study found that women who used Essure[®] as a means for permanent sterilization were ten times more likely to undergo re-operation due to device related complications and injuries compared to women who underwent tubal ligation.¹⁰⁷

323. The study reported that although Essure[®] is advertised as a surgery-free alternative to the minimally invasive laparoscopic surgery, women who had the Essure[®] implant often required a subsequent major surgery due to complications resulting from Essure[®], and at far greater rates than the traditional option.¹⁰⁸

324. The authors also analyzed the Essure[®] MAUDE data and indicated that most of the adverse events reported by patients with Essure[®] were for injuries that would require and did

¹⁰⁴ See “Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study” available online at: <http://www.bmj.com/content/351/bmj.h5162>.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

require a subsequent surgical operation.¹⁰⁹ Such injuries included pelvic pain, hemorrhage, and device migration or incompatibility.

325. Reports of chronic pain, hemorrhage, and device migration, which necessitate surgical intervention, are indeed serious injuries and are therefore reportable events.¹¹⁰

326. Conceptus and Bayer did not submit any MDR reportable events derived from this study to the FDA.

327. Bayer still falsely claims to this day that Essure[®] is safer than undergoing tubal ligation.

b. Essure[®] Is Not as Effective as Alternative Methods.

328. Women with Essure[®] are more likely to get pregnant than women who undergo a tubal ligation.

329. In March of 2014, the online medical journal Conception published a study entitled *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization*, which compared the expected probability of pregnancy after hysteroscopic sterilization (Essure[®]) with laparoscopic sterilization based on available data using decision analysis.¹¹¹

330. The study analysis took into account uncertainties in successful placement of coils, return for follow-up confirmation testing and successful blockage of tubes. Using real-life circumstances, the authors concluded that at all points in time after the sterilization procedure, the

¹⁰⁹ *Id.*

¹¹⁰ 21 C.F.R. § 803.3 (2012).

¹¹¹ See “Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization” available at: <http://www.contraceptionjournal.org/pb/assets/raw/Health%20Advance/journals/contr/CON-8309-FINAL.pdf> (last visited February 8, 2018).

initial and cumulative risk of pregnancy after sterilization is higher in women who undergo hysteroscopic sterilization than either laparoscopic band or bipolar sterilization.¹¹²

331. The study found that the expected pregnancy rates per 1000 women at one (1) year are 57, 7 and 3 for hysteroscopic sterilization, laparoscopic silicone rubber band application and laparoscopic bipolar coagulation, respectively. At ten (10) years, the cumulative pregnancy rates per 1000 women are 96, 24 and 30, respectively.¹¹³

332. This means that the probability of getting pregnant at one (1) year and over ten (10) years is higher in women who receive Essure® as compared to laparoscopic sterilization.¹¹⁴

333. Essure® sterilization failure rates after typical use in the community by a variety of physicians on a variety of patients are significantly higher than the failure rates reported to the FDA by the manufacturer in its own highly controlled study.

334. However, Bayer still falsely claims to this day that Essure® is more effective than undergoing tubal ligation.

c. Leading Practitioners Have Criticized Conceptus for Its Lack of Transparency.

335. Experts in the field of gynecology disapprove of Conceptus' and Bayer's failure to provide information to the public.

336. On September 23, 2015, the New England Journal of Medicine published an article entitled *Revisiting Essure – Toward Safe and Effective Sterilization*. Authored by several prominent gynecologists, the article expressed concerns about the inadequacy of Essure®'s premarketing and postmarketing studies.¹¹⁵

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ See “Revisiting Essure – Toward Safe and Effective Sterilization” available online at: <http://www.nejm.org/doi/full/10.1056/NEJMp1510514>.

337. More specifically, the authors identified problems relative to incomplete follow-up with patients and biased results.

338. Ultimately, the authors concluded that many of the Essure[®] adverse events and safety concerns, along with problems with the device's effectiveness, might have been detected sooner or avoided altogether if there had been higher-quality premarketing and postmarketing evaluations and more timely and transparent dissemination of study results by the manufacturers.¹¹⁶

339. Coinciding with other developing understandings, the article notes that evidence suggests that Essure[®] is neither as effective nor as safe as the premarketing-approval evaluation indicated.¹¹⁷

8. The Revelation of Safety Information in the Public Leads to the Inevitable: FDA Mandates Major Changes to Essure[®] Sales.

340. As thousands of reports about Essure[®]'s true safety risks became public recently, the FDA forced drastic changes to the product's warning label and took aggressive measures to ensure that patients are fully informed of the risks.

341. Patients and physicians have reported to the FDA upwards of 13,000 adverse events related to Essure[®] since October 2013. This significant increase prompted the FDA to convene a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee to examine safety concerns about Essure[®] raised by patients and cited in MDRs.

342. The meeting was held on September 24, 2015, and FDA heard available scientific data pertaining to Essure[®]'s safety and effectiveness, expert scientific and clinical opinions on the risks and benefits of Essure[®], and concerns and experiences of women implanted with the device.

¹¹⁶ *Id.*

¹¹⁷ *Id.*

343. On February 29, 2016 the FDA announced that it would force a major change to the Essure[®] warning label and also require all women considering receiving Essure[®] to fill out a “Patient Decision Checklist” to ensure that they are fully informed of the true risks.¹¹⁸

344. The FDA stated that such warnings are needed for a woman to understand the risks as compared to alternative options and then decide whether the product is right for her.¹¹⁹

345. The new warning and checklist were finally approved on November 15, 2016 and will change the risk/benefit profile of Essure[®] for all potential patients. It will reveal the alternatives as far better choices for many women. It will lead to far less patients choosing to use the Essure[®] system.

346. This result is why Conceptus and Bayer withheld safety information from the FDA and the public for years.

347. Conceptus and Bayer knew that if the true risks of Essure[®] were known to the FDA, then they would inevitably be communicated to physicians and women.

348. Conceptus and Bayer knew that if physicians and women understood the true risks of Essure[®], then sales of the device would be devastated.

349. Conceptus and Bayer withheld thousands of complaints of adverse events from the FDA for years to protect and promote the false perception that the Essure[®] device was safe.

350. If Essure[®] was ever perceived as unsafe, or not as safe as alternative birth control methods, then the device would not have achieved market acceptance and the company would fail.

351. To protect sales and revenue, Conceptus and Bayer purposefully ignored their mandatory federal reporting requirements and actively hid safety information from the public for as long as they could.

¹¹⁸ See <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm488313.htm> (last updated February 29, 2016).

¹¹⁹ *Id.*

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a. FDA Orders Bayer to Give Warnings Indicating the Highest Level of Risk.

352. In February of 2016 the FDA determined that a boxed warning needed to be a part of the Essure[®] warning label.

353. The FDA reserves boxed warnings for only the most serious adverse events, and they indicate the highest level of risk.

354. On March 4, 2016, the FDA noted that it would receive public input for the following suggested warning:

WARNING: Some patients implanted with the Essure System for Permanent Birth Control have reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions. Some of these reported events resulted in device removal that required abdominal surgery. This information should be shared with patients considering sterilization with the Essure device during discussion of the benefits and risks of the device.¹²⁰

355. On October 31, 2016, the FDA issued the following final guidance, “Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization,” which stated that “a boxed warning should be part of the labeling for a permanent, hysteroscopically-placed tubal implant for sterilization...” The FDA states that this warning should:

- Note the types of significant and/or common adverse events that may be associated with the device and its insertion, use, and/or removal procedure, including those noted in clinical trials, as well as those reported in other device use experience.
- Include a statement noting that these risks should be conveyed to the patient during the decision-making process.¹²¹

356. The October 2016 Boxed Warning Example issued by the FDA was implemented in November 2016, and states as follows:

¹²⁰ FDA Draft Guidance on Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization, issued March 4, 2016.

¹²¹ See “Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization,” at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM488020.pdf>.

WARNING: Some patients implanted with the Essure System for Permanent Birth Control have experienced and/or reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the Essure System for Permanent Birth Control during discussion of the benefits and risks of the device.¹²²

357. This boxed warning directly addresses side effects that Conceptus and Bayer had been cited for hiding from the FDA and the public for years.

358. The advent of this warning illustrates the significance of Conceptus' and Bayer's illegal and immoral behavior.

359. Conceptus and Bayer hid from patients the safety information about the most serious adverse events and the highest levels of risk.

360. If Conceptus and Bayer had not violated federal reporting violations, the public would have known about these safety risks years earlier. Thousands of women who decided to have the Essure® device implanted would have received the knowledge that they deserved, and thousands of injuries could have been prevented.

361. Conceptus and Bayer could have prevented this problem by updating their warnings to patients.

362. The Essure® warning label has never been adequate.

363. Conceptus and Bayer did all in their power to keep serious side effects and warnings off of the Essure® label for years.

¹²² *Id.* at pg. 9; see also http://labeling.bayerhealthcare.com/html/products/pi/essure_pib_en.pdf; and see http://labeling.bayerhealthcare.com/html/products/pi/essure_ifu.pdf.

364. Over the course of many years, despite knowing of hundreds of instances where the Essure® device had migrated from its proper position, Conceptus did not warn of this potential problem.

365. After being caught by the FDA in 2011 for not reporting migration events, the company still refused to warn about this problem on its label.

366. It was not until 2013 that Conceptus even acknowledged migration events on the Essure® label.

367. At that time, Conceptus changed the warning label to state only that "There are reports of the Essure® insert migrating."

368. This warning gravely downplayed the true incidence of risk that a woman's Essure® coils might migrate.

369. Conceptus should have been adequately informing women about migrations.

370. This issue illustrates Conceptus' policy of deliberately refusing to provide adequate warnings to physicians and patients.

371. For years Conceptus and Bayer have downplayed on the Essure® warning label the true risks of migration, as well as perforation, persistent pain, allergy or hypersensitivity reactions, autoimmune-like reactions, the likelihood of reoperation, and other serious side effects.

372. The FDA has now forced what could and should have been done years ago.

b. FDA takes Drastic Measures to Ensure Patients are Fully Informed.

373. Because Conceptus and Bayer denied thousands of women the information that they deserved, every potential Essure® patient is now required to receive and sign a detailed checklist specifically tailored to the risks associated with the device.

374. The Patient Decision Checklist requires a patient's initials and signature six separate times.

375. The checklist specifically warns of device migration and perforation of organs, side effects that Conceptus and Bayer had been cited for hiding from the FDA and the public for years.

376. The checklist also specifically warns that some women may develop allergic reactions following implantation of Essure[®], which could cause symptoms such as rashes or itching.

377. Most importantly, the checklist describes the review of its form as a critical step in deciding whether to have the Essure[®] device implanted, and suggests that a woman should carefully consider the risks before making the decision.

378. The checklist has a major impact on the risk/benefit profile of the device.

379. The U.S. Food and Drug Administration (FDA) recently announced it is investigating new reports of problems with Essure[®]. In 2017, the FDA received more than 12,000 reports regarding new complaints about issues with the device, with and over 90% of those related to reports which involved potential removal of the birth control device.

380. Commissioner Gottlieb issued a statement in March 2018 announcing the FDA is opening a new investigation after over 12,000 new complaints about the device were filed in 2017, most of which were filed in the last three months of the year. Most of that newly filed information involves problems related to potential removal of the medical device and demonstrates that Bayer has known about these problems for years.

381. Further, on April 9, 2018, the FDA restricted the “sale and distribution of Essure[®] to protect women and to require that patients receive risk information.”¹²³ The FDA issued an order requiring a unique restriction, wherein only healthcare providers who provide patients with the “Patient-Doctor Discussion Checklist – Acceptance of Risk and Informed Decision

¹²³ <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm604098.htm>.

Acknowledgement” are permitted to use Essure®. The patient must be given an opportunity to sign the acknowledgement, and the implanting physician must sign it.

382. “Since the FDA ordered Bayer to conduct a post-market study, and then to add a boxed warning and a patient decision checklist to the labeling, there has been an approximately 70 percent decline in sales of Essure in the U.S. The FDA has determined, however, that some women still are not receiving information about the known risks of Essure before implantation.”¹²⁴

383. “We’ve been closely evaluating new information on the use of Essure, and based on our review of a growing body of evidence, we believe this product requires additional, meaningful safeguards to ensure women are able to make informed decisions about risk when considering this option,” said FDA Commissioner Scott Gottlieb, M.D. “We take the concerns of all women affected by Essure very seriously. I’ve personally had the opportunity to meet with several women and hear their important concerns about this product. Despite previous efforts to alert women to the potential complications of Essure, we know that some patients still aren’t receiving this important information. That is simply unacceptable. Every single woman receiving this device should fully understand the associated risks.”¹²⁵

384. “The FDA will review and monitor Bayer’s plan to ensure the company complies with the restriction. The FDA plans to enforce these requirements and will take appropriate action for a failure to comply, including applicable criminal and civil penalties.”¹²⁶

385. Finally, on July 20, 2018, Bayer announced its plans to halt Essure® sales in the United States, effective December 31, 2018¹²⁷.

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ See, “Statement from FDA Commissioner Scott Gottlieb, M.D., on manufacturer announcement to halt Essure sales in the U.S.; agency’s continued commitment to postmarket review of Essure and keeping women informed,” July 20, 2018, located at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm614123.htm>.

G. CONCEPTUS' AND BAYER'S PARTICIPATION IN THE COVERING UP OF AND FAILURE TO ADEQUATELY WARN OF SERIOUS ADVERSE EVENTS AND INCREASED RISKS AND COMPLICATIONS ASSOCIATED WITH ESSURE® CAUSED PLAINTIFFS' INJURIES.

386. A manufacturer has the duty to provide adequate and timely warnings regarding increased risks and dangers associated with the foreseeable uses of its product.

387. Conceptus and Bayer grossly failed to satisfy their duties mandated by federal law, the Essure® PMA, and state common law duties.

388. Conceptus and Bayer did not provide adequate and timely warnings or instructions regarding the true risks of Essure®.

389. Conceptus and Bayer disseminated misleading and false information concerning the true risks of Essure®.

390. Conceptus and Bayer purposefully concealed the serious increased risks and complications associated with Essure®.

391. Conceptus and Bayer failed to take the required actions when they learned that Essure® was causing thousands of problems in patients.

392. Bayer cannot and should not be permitted to absolve itself from liability by pointing to the FDCA or the MDA, claiming preemption, when it was Conceptus and Bayer who chose to deliberately conceal their knowledge of the increased risks, complications, and the serious and dangerous adverse side effects associated with Essure®.

393. Bayer cannot and should not be permitted to absolve itself from liability when it was Conceptus and Bayer who, in violation of federal law and the PMA, concealed and failed to report the true number of adverse events being reported by women with Essure®.

394. A medical device manufacturer only receives the benefits afforded by federal law, i.e. the FDCA and MDA, when it abides by federal law.

395. Federal law requires that a manufacturer report all known adverse events associated with a medical device to the FDA.

396. Not only did Conceptus and Bayer not provide the Plaintiffs' physicians nor Plaintiffs with the necessary information in order to make an informed decision in the best interests of Plaintiffs' health, but they purposefully deceived Plaintiffs' physicians and the Plaintiffs as to the safety and efficacy of Essure®.

397. Conceptus and Bayer did not discharge their duty, required by federal law, the Essure® PMA, and state common law duties to adequately and fully warn and inform Plaintiffs' physicians and Plaintiffs of the known dangers and increased risks associated with the use of Essure®.

398. Plaintiffs' physicians and Plaintiffs reasonably relied, and did rely, on Conceptus and Bayer's misrepresentations and concealments.

399. Moreover, Plaintiffs would not have consented to undergo the Essure® procedure had they been fully informed of its increased dangers, risks, and adverse consequences.

400. As a direct and proximate result of Conceptus and Bayer's fraudulent concealment and misrepresentations concerning material health and safety risks associated with Essure®, Plaintiffs were injured and suffered and will continue to suffer injuries, damages, and economic loss.

401. As a direct and proximate result of Conceptus and Bayer's fraudulent concealment and misrepresentations concerning material health and safety risks associated with Essure®, Plaintiffs have been injured and incurred damages, including but not limited to medical and hospital expenses, physical and mental pain and suffering, and loss of the quality and enjoyment of life as a result.

V. EQUITABLE TOLLING/FRAUDULENT CONCEALMENT

402. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

403. Conceptus and Bayer's failure to report, document, or follow up on the known adverse event complaints, and concealment of adverse events, known defects, serious increased risks, dangers, and complications, constitutes fraudulent concealment that equitably tolls any proffered statute of limitation that may otherwise bar the recovery sought by Plaintiffs herein. Plaintiffs herein have therefore satisfied applicable statutes of limitations and statutes of repose.

404. Bayer is estopped from relying on any statute of limitations defense because it continued to refute and deny reports and studies questioning the safety of Essure[®], actively and intentionally concealed the defects, suppressed reports and adverse information, sponsored and paid for studies which falsely characterized the risks and benefits of Essure[®], failed to satisfy FDA and PMA requirements, failed to satisfy FDA and PMA notification requirements, and failed to disclose known dangerous defects and serious increased risks and complications to physicians and the Plaintiffs.

405. Instead, Conceptus and Bayer continued/continues to represent that Essure[®] was/is safer, more effective and the best alternative for permanent female sterilization, all the while they knew that this is absolutely false, even after the recent Cornell study was published and patient complaints accumulated in the thousands.

406. Conceptus and Bayer did the above acts which were and are illegal under federal law, the PMA and parallel state law, to effectively market Essure[®] and encourage physicians, including Plaintiffs' physicians, to recommend and perform the Essure[®] procedure.

407. Conceptus and Bayer did the above acts which were and are illegal under federal law, the PMA and parallel state law, to encourage patients, including Plaintiffs, to undergo the Essure[®] procedure rather than choose an alternative procedure, such as a traditional tubal ligation.

408. At all relevant times, Conceptus and Bayer were under a continuing duty under federal law, the PMA and parallel state laws to disclose the true character, quality, and nature of the increased risks, adverse events, and dangers associated with Essure[®].

409. As a result of Conceptus' and Bayer's concealment of the true character, quality and nature of their product, they are estopped from relying on any statute of limitations defense.

410. Conceptus and Bayer furthered their fraudulent concealment through act and omission, including misrepresenting known dangers and/or defects in Essure[®] and/or arising out of the use of Essure[®] and a continued and systematic failure to disclose and/or cover-up such information from/to the Plaintiffs, Plaintiffs' physicians, and the public.

411. Conceptus and Bayer's acts and omissions, before, during and/or after the acts causing Plaintiffs injuries, prevented Plaintiffs and/or Plaintiffs' physicians from discovering the injuries or cause thereof until recently.

412. Conceptus' and Bayer's conduct, because it was purposely committed, was known or should have been known by them to be dangerous, heedless, reckless, and without regard to the consequences or the rights and safety of the Plaintiffs.

VI. GENERAL ALLEGATIONS

413. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

414. At all relevant times, Essure[®] was researched, developed, manufactured, marketed, promoted, advertised, sold and distributed by Conceptus and Bayer.

415. Conceptus and Bayer negligently, carelessly, and/or recklessly manufactured, marketed, advertised, promoted, sold and distributed Essure[®] as a safe and effective device to be used for permanent female sterilization.

416. Conceptus and Bayer knew, and/or had reason to know, that Essure[®] was defective, unreasonably dangerous and not safe because of the thousands of adverse events that both companies knew about.

Representations

417. Conceptus and Bayer negligently, carelessly, recklessly, and/or intentionally promoted Essure[®] to physicians and patients, including the Plaintiffs and Plaintiffs' physicians.

418. Conceptus and Bayer downplayed to physicians and patients, including Plaintiffs and Plaintiffs' physicians, the dangerous side effects of Essure[®], with an intent to deceive.

419. Conceptus and Bayer misrepresented the safety of Essure[®] to physicians and patients, including Plaintiffs and Plaintiffs' physicians.

420. Conceptus and Bayer willfully and/or intentionally failed to warn and/or alert physicians and patients, including Plaintiffs and Plaintiffs' physicians, of the increased risks and significant dangers resulting from being implanted with the Essure[®] device.

421. Conceptus and Bayer knew and/or had reason to know, that their representations and suggestions to physicians that Essure[®] was safe and more effective than alternative permanent sterilization methods were materially false and misleading such that physicians and patients, including Plaintiffs and Plaintiffs' physicians, would rely on such representations.

422. Conceptus and Bayer knew or should have known and/or recklessly disregarded the materially incomplete, false, and misleading nature of the information that they caused to be disseminated to the public and to physicians, including Plaintiffs and Plaintiffs' physicians, as part of their surreptitious campaign to promote Essure[®].

423. Any warnings Conceptus and Bayer may have issued concerning the risks and dangers of Essure[®] were inadequate and insufficient in light of their contradictory prior, contemporaneous and continuing illegal promotional efforts of Essure[®] to hide or downplay the true risks and serious dangers of the device.

424. The ongoing scheme described herein could not have been perpetrated over a substantial period of time, as has occurred here, without knowledge and complicity of personnel at the highest levels of Conceptus and Bayer, including the corporate officers and directors.

425. Conceptus and Bayer knew and/or had reason to know of the likelihood of serious injuries caused by the promotion, sale, and distribution of Essure[®], but they concealed this information and did not warn the FDA, Plaintiffs or Plaintiffs' physicians, preventing Plaintiffs and Plaintiffs' physicians from making informed choices in selecting alternative sterilization procedures prior to Plaintiffs' Essure[®] implantation procedure and preventing Plaintiffs and Plaintiffs' physicians from timely discovering Plaintiffs' injuries.

Causation

426. Plaintiffs would not have consented to undergo the Essure[®] procedure had Plaintiffs known of or been fully and adequately informed by Conceptus and Bayer of the true increased risks, hazards, and serious dangers of Essure[®].

427. Plaintiffs and Plaintiffs' physicians reasonably relied on Defendants' representations and omissions regarding the safety and efficacy of Essure[®].

428. Plaintiffs and Plaintiffs' physicians did not know of the specific increased risks and serious dangers, and/or were misled by Conceptus and Bayer, who knew or should have known of the true risks and dangers, but consciously chose not to inform Plaintiffs or their physicians of those risks and to actively misrepresent those risks and dangers to the Plaintiffs and Plaintiffs' physicians. Conceptus' and Bayer's promotion and marketing of Essure[®] caused Plaintiffs'

physicians to decide to recommend and implant Essure® in Plaintiffs. Plaintiffs' physicians would not have recommended and performed the Essure® procedure in the absence of Conceptus' and Bayer's false and misleading promotion.

Damages

429. Plaintiffs have suffered serious personal injuries as a direct and proximate result of Conceptus' and Bayer's illegal misconduct.

430. As a direct and proximate result of Conceptus' and Bayer's illegal conduct, Plaintiffs have suffered and will continue to suffer from severe injuries and damages, including but not limited to autoimmune-like symptoms, irregular heavy menstrual cycle bleeding, organ perforation, and severe chronic pain which required surgical intervention to remove the Essure® coils and/or will require surgical intervention to remove the Essure® coils in the future.

431. As a result of Conceptus' and Bayer's failure to warn of the risks, dangers, and adverse events associated with Essure® as manufactured, promoted, sold and supplied by both companies, and as a result of the negligence, callousness, and other wrongdoing and misconduct of Conceptus and Bayer as described herein:

- A) Plaintiffs have been injured and suffered and will continue to suffer injuries to their body and mind, the exact nature of which are not completely known to date;
- B) Plaintiffs have sustained and will continue to sustain economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown;
- C) Plaintiffs have incurred and will be required to incur additional medical expenses in the future to care for themselves as a result of the injuries and damages Plaintiffs have suffered;
- D) Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interests thereon and costs.

432. Plaintiffs had no reason until recently to suspect that their injuries were caused by Essure®. Thus, Plaintiffs did not know and could not have known and through the exercise of reasonable diligence, that the Essure® device caused their injuries.

433. Plaintiffs herein brings their causes of action within the applicable statute of limitation. Specifically, Plaintiffs bring their actions within the prescribed time limits following their injuries and their knowledge of the wrongful cause. Prior to such time, Plaintiffs did not know nor had reason to know of their injuries and/or the wrongful cause thereof.

434. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

VII. SPECIFIC PLAINTIFFS' ALLEGATIONS

A. KEISHA WISE

435. Plaintiff Wise is thirty-six (36) years old and resides in Pittsburgh, Allegheny County, Pennsylvania.

1. Initial Essure® Procedure:

436. On or around August 16, 2011, Plaintiff Wise underwent the Essure® procedure (ESS305, Lot #855630) under general anesthesia at Magee-Womens Hospital in Pittsburgh, Allegheny County, Pennsylvania.

437. Harati Tatineni, MD, implanted the Essure® device in Plaintiff Wise.

438. Further, Plaintiff Wise was not informed that the Essure® procedure as marketed was not intended to take place under general anesthesia and that the balance of risks and benefits of Essure® versus tubal ligation was unfavorable to Essure® under such circumstances.

2. Post Essure® Procedure Condition and Treatment:

439. Plaintiff Wise underwent a HSG exam on or about December 27, 2011, which showed bilateral occlusion of both fallopian tubes.

440. Plaintiff Wise's post-procedure course has been marked by abdominal and back pain, menorrhagia, dysmenorrhea, irregular menstrual cycles, anemia, bloating, and frequent urinary tract and vaginal infections. She never experienced this combination of symptoms prior to Essure®.

441. Before Essure®, Plaintiff's menses were light, lasted three to five days, and she had minimal pain. After Essure®, she experienced constant heavy bleeding with clots and cramping. There were times she had trouble getting out of bed. Her bleeding was so heavy that she had to change an overnight pad every one to two hours.

442. On or around July 26, 2013, Plaintiff Wise presented to Womancare Associates-Douletree ("WCA") reporting a change in her menstrual period, frequent urinary tract infections, and vaginal discharge and odor. She further reported getting her period more than once a month and the flow was darker. She was assessed with possible urinary tract infection and possible bacterial vaginosis. A pelvic ultrasound was ordered.

443. Plaintiff Wise underwent a transabdominal pelvic ultrasound on or about August 17, 2013, to evaluate her irregular bleeding. The findings were normal and noted "Essure is seen in the cornual regions of the uterus."

444. On or about August 26, 2013, Plaintiff Wise again presented to WCA with complaints of irregular vaginal bleeding. She was assessed with irregular vaginal bleeding. Since the cause of her bleeding could not be determined, she was prescribed hormonal birth control pills for menstrual regulation.

445. On or around January 13, 2014, Plaintiff Wise presented to Western Pennsylvania OB/GYN Associates ("WPOB") complaining of vaginal discharge and odor and possible urinary tract infection. Her assessments included vaginal discharge and urinary tract infection.

446. On or about February 5, 2015, Plaintiff Wise again presented to WPOB with complaints of “ongoing menses” for the past six weeks. She was assessed with menorrhagia and was again prescribed hormonal birth control pills.

447. After not receiving answers from her previous physicians, Plaintiff Wise sought treatment from Dr. Arthur Signorella for complaints of pelvic pain. Dr. Signorella ordered a transabdominal pelvic/vaginal ultrasound which was performed on or about February 3, 2017. The ultrasound noted “Essure in situ bilaterally.”

448. On or around March 9, 2017, Plaintiff Wise underwent a laparoscopic supracervical hysterectomy, bilateral salpingectomy and cystoscopy performed by Dr. Arthur Signorella at St. Clair Hospital in Pittsburgh, Pennsylvania due to her continued menorrhagia and pelvic pain. The pathology report noted “chronic endometritis” and the “tissue surrounding the right and left fallopian tube coils has very minimal collagenous fibrosis and fibroblastic proliferation with focal chronic inflammation.”

449. Plaintiff Wise’s symptoms have largely resolved since her surgery to remove the Essure® device and only experiences vaginal infections at times. Until the removal, neither she nor her doctors could clearly correlate her problems as being associated with the device. After the removal, the cause of her problems became obvious due to their resolution.

450. Plaintiff Wise did not realize that she had a legal remedy due to her injuries from Essure® until she saw a legal advertisement describing symptoms like hers which were also being experienced and suffered by thousands of other women who had been implanted with the Essure® device. It was at this time that she truly understood that her symptoms were related to Essure® and the legal options available to her.

B. AMY DANISAVICH

451. Plaintiff Danisavich is forty-one (41) years old and resides in Cumbola, Schuylkill County, Pennsylvania.

1. Initial Essure® Procedure:

452. On or around April 10, 2006, Plaintiff Danisavich underwent the Essure® procedure under general anesthesia at The Pottsville Hospital and Warne Clinic in Pottsville, Schuylkill County, Pennsylvania.

453. David Krewson, DO, implanted the Essure® device in Plaintiff Danisavich.

454. Further, Plaintiff Danisavich was not informed that the Essure® procedure as marketed was not intended to take place under general anesthesia and that the balance of risks and benefits of Essure® versus tubal ligation was unfavorable to Essure® under such circumstances.

455. Plaintiff Danisavich went to Dr. Krewson to inquire about permanent birth control, such as bilateral tubal ligation, but was directed towards Essure®. Dr. Krewson told her that Essure® was a quick procedure with little-to-no downtime.

2. Post Essure® Procedure Condition and Treatment:

456. Plaintiff Danisavich's post-procedure course has been marked by pain, rashes, hair loss, night sweats, severe dysmenorrhea and menometrorrhagia. Before Essure®, Plaintiff had not experienced this combination of symptoms while not on birth control. Her menstrual cycles were normal, and she had no problem with going about her daily life.

457. For the next three years, Plaintiff Danisavich repeatedly sought treatment for her symptoms, but no physician was able to determine their cause.

458. For example, on or around December 3, 2009, Plaintiff Danisavich presented for an office visit with Whitney Pollock, DO, with complaints of menorrhagia and menopausal

symptoms. She underwent a pelvic ultrasound which showed bilateral follicular cysts, Nabothian cysts and a thickened endometrium. She was provided with Novasure literature.

459. On or around December 17, 2009, Plaintiff Danisavich presented for a follow-up visit with Dr. Pollock and reported experiencing heavy menstrual cycles with cramping. She was prescribed an oral contraceptive and scheduled for a dilation & curettage (“D&C”) and possible ablation.

460. On or around January 25, 2010, Plaintiff Danisavich underwent a diagnostic hysteroscopy and D&C performed by Dr. Pollock. The procedure report noted that only the left Essure® coil was visualized, and the right Essure® coil was not seen.

461. Plaintiff Danisavich presented for a post-operative visit with Dr. Pollock on or around February 15, 2010. She underwent an x-ray of her abdomen which revealed “[t]he coil on the right appears to project at a grossly identical height referable to the sacrum allowing for technical differences. The coil on the left projects slightly lower and more lateral...” Dr. Pollock instructed her to continue her birth control pills for menstrual regulation.

462. On or around March 2, 2010, Plaintiff Danisavich presented for a follow-up visit with Dr. Pollock. She reported continued abdominal pain in the right lower quadrant, leg cramps and vertigo due to the misplaced right Essure® coil. Dr. Pollock advised that the x-ray confirmed bilateral coil placement and discussed changing oral contraceptives versus laparoscopy-assisted vaginal hysterectomy/unilateral oophorectomy.

463. Finally, on or around May 10, 2010, Plaintiff Danisavich underwent a laparoscopic-assisted vaginal hysterectomy and right salpingo-oophorectomy performed by Dr. Pollock at Saint Catherine Medical Center in Ashland, Pennsylvania due to her menorrhagia and pelvic pain. As to the right ovary, the pathology report noted follicular cysts, cystic follicles and a corpus luteum. The pathology report failed to note an Essure® coil within the right fallopian tube.

464. Plaintiff Danisavich's symptoms have largely resolved after her surgery; however, she continues to suffer from hip pain and left-sided abdominal pain. It is possible that the left Essure[®] coil is still located in her body, causing her ongoing symptoms. She is unable to seek additional treatment to confirm the possibility that an Essure[®] coil may still be in her as she does not presently have health insurance.

465. Sometime in or around November 2016, Plaintiff Danisavich saw a legal advertisement describing a potential action to be filed against the manufacturers of the Essure[®] device. It was not until seeing this advertisement, which described symptoms like hers that were also being experienced by thousands of other women who had been implanted with the Essure[®] device, that Plaintiff could reasonably have understood that her symptoms were related to Essure[®] and the legal options available to her.

C. JACKIE MEYER

466. Plaintiff Meyer is thirty (30) years old and resides in New Castle, Lawrence County, Pennsylvania.

1. Initial Essure[®] Procedure:

467. Upon information and belief, in or around October 2014, Plaintiff Meyer underwent the Essure[®] procedure under general anesthesia at the University of Pittsburgh Medical Center - Jameson ("UPMC") in New Castle, Pennsylvania. Amy Shannon, MD implanted the Essure[®] device in Plaintiff Meyer.

468. Further, Plaintiff Meyer was not informed that the Essure[®] procedure as marketed was not intended to take place under general anesthesia and that the balance of risks and benefits of Essure[®] versus tubal ligation was unfavorable to Essure[®] under such circumstances.

469. Plaintiff Meyer was directed toward Essure[®] by her providers. It was her understanding that Essure[®] had a shorter recovery period than a bilateral tubal ligation.

2. Post Essure® Procedure Condition and Treatment:

470. Plaintiff Meyer's post-procedure course has been marked by increasingly severe pain and discomfort, including, but not limited to, irregular and heavy menstrual periods, pelvic pain, abdominal pain, bloating, hives and rashes, dental issues, severe headaches, chronic fatigue, chest pain, shortness of breath, frequent urinary tract infections, and hair loss. Before Essure®, Plaintiff Meyer had not experienced this combination of symptoms, and she had no problem with going about her daily life.

471. On or around July 8, 2015, Plaintiff Meyer underwent a HSG exam at UPMC which indicated bilateral occlusion of the fallopian tubes.

472. Since undergoing the Essure® procedure, Plaintiff Meyer repeatedly sought treatment for her symptoms from various medical providers in New Castle, Pennsylvania and Elwood, Pennsylvania.

473. Upon information and belief, sometime in or around February 2016, Plaintiff Meyer tested positive for an allergy to nickel.

474. On or around February 24, 2016, Plaintiff Meyer presented to Dr. Sheila Burick complaining of shortness of breath, hives which associated itching that she has been experiencing on and off for about 3 to 4 months. She further indicated that she may be allergic to the Essure® device. She was diagnosed with a nickel allergy.

475. On or around February 26, 2016, Dr. Burick provided Plaintiff Meyer with a letter recommending removal of the Essure® device.

476. On or around May 15, 2016, Plaintiff Meyer presented to Anthony Elisco, MD, complaining of headaches and associated photophobia.

477. On or around May 16, 2016, Plaintiff Meyer presented to Elizabeth Wirth, MD for a removal consultation of the Essure® device. She reported that since the Essure® device was

placed, she breaks out in hives all over her face, experiences shortness of breath, and has experienced an increase in the severity of headaches.

478. On or about July 16, 2016, Plaintiff Meyer underwent a laparoscopic bilateral salpingectomy to remove the Essure[®] device performed by Elizabeth Wirth, MD, at the University of Pittsburgh Medical Center in Pittsburgh, Pennsylvania. The pathology report noted a “[s]ingle Essure coil present.”

479. Plaintiff Meyer did not realize that she had a legal remedy due to her injuries from Essure[®] until she saw a legal advertisement, sometime on or about June 5, 2017, describing symptoms like hers which were also being experienced and suffered by thousands of other women who had been implanted with the Essure[®] device. It was at this time that she truly understood that her symptoms were related to Essure[®] and the legal options available to her.

D. CHELSEA DEYARMIN

480. Plaintiff Deyarmin is twenty-seven (27) years old and resides in Altoona, Blair County, Pennsylvania.

1. Initial Essure[®] Procedure:

481. Upon information and belief, sometime in or around July 2014, Plaintiff Deyarmin underwent the Essure[®] procedure under general anesthesia at the University of Pittsburgh Medical Center - Altoona (“UPMC”) in Altoona, Pennsylvania.

482. John Kennedy, MD, implanted the Essure[®] device in Plaintiff Deyarmin.

483. Further, Plaintiff Deyarmin was not informed that the Essure[®] procedure as marketed was not intended to take place under general anesthesia and that the balance of risks and benefits of Essure[®] versus tubal ligation was unfavorable to Essure[®] under such circumstances.

484. Plaintiff Deyarmin was directed toward Essure[®] by her providers. It was her understanding that Essure[®] was as safe or safer than a bilateral tubal ligation.

2. Post Essure® Procedure Condition and Treatment:

485. Plaintiff Deyarmin's post-procedure course has been marked by severe pelvic pain and discomfort, including, but not limited to, abdominal pain, dyspareunia, weight gain, bloating, dental issues, hair loss, joint pain, frequent yeast infections, chronic fatigue, dizziness, a metallic taste in her mouth and severe migraines. Before Essure®, she had not experienced this combination of symptoms, and she had no problem going about her daily life.

486. Upon information and belief, Plaintiff Deyarmin had a HSG exam completed sometime in or around October 2014 which demonstrated occlusion of the left fallopian tube.

487. Since undergoing the Essure® procedure, Plaintiff Deyarmin repeatedly sought treatment for her symptoms, but none of her treating physicians were able to determine their cause.

488. On or around November 16, 2016, Plaintiff Deyarmin underwent removal of the Essure® device at UMPC - Altoona in Altoona, Pennsylvania.

489. Plaintiff Deyarmin did not realize that she had a legal remedy due to her injuries from Essure® until she saw a legal advertisement, sometime in or around September 2016, describing symptoms like hers which were also being experienced by thousands of other women who had been implanted with the Essure® device. It was at this time that she truly understood that her symptoms were related to Essure® and the legal options available to her.

E. RAEMARIE COLEMAN

490. Plaintiff Coleman is forty (40) years old and resides in Philadelphia, Philadelphia County, Pennsylvania.

1. Initial Essure® Procedure:

491. Upon information and belief, on or around August 10, 2012, Plaintiff Coleman underwent the Essure® procedure under general anesthesia at Einstein Medical Center in Philadelphia, Pennsylvania.

492. Teresa Robb, MD, implanted the Essure® device in Plaintiff Coleman.

493. Further, Plaintiff Coleman was not informed that the Essure® procedure was not intended to take place under general anesthesia and that the balance of risks and benefits of Essure® versus tubal ligation was unfavorable to Essure® under such circumstances.

494. Plaintiff Coleman was directed toward Essure® by her providers. It was her understanding that Essure® was less invasive than tubal ligation.

2. Post Essure® Procedure Condition and Treatment:

495. Plaintiff Coleman's post-procedure course has been marked by severe pain and discomfort, including, but not limited to, heavy menstrual periods, severe cramping, low back pain, abdominal bloating, weight gain, chronic fatigue, memory loss, severe migraines and a migrated coil. Before Essure®, she had not experienced this combination of symptoms and she had no problem going about her daily life.

496. Since undergoing the Essure® procedure, Plaintiff Coleman repeatedly sought treatment for her symptoms, but none of her treating physicians were able to determine their cause.

497. Upon information and belief, sometime in or around 2016, Plaintiff Coleman underwent an ultrasound at Einstein Medical Center which revealed that one Essure® coil had migrated from her fallopian tube and was imbedded in her uterus.

498. Plaintiff Coleman's symptoms have not resolved as she still has the Essure® device surgically implanted. Further, she lacks the financial ability to seek removal of the Essure® device at this time but she continues to seek treatment for her symptoms.

499. Plaintiff Coleman did not realize, until sometime in or around August of 2016 when she began to research the Essure® device and her symptoms, that the same or similar symptoms were also being experienced and suffered by thousands of other women who had been implanted

with the Essure[®] device. It was at this time that Plaintiff Coleman understood that her symptoms could be related to Essure[®].

F. TARA DAUGHERTY

500. Plaintiff Daugherty is thirty-one (31) years old and resides in Morgantown, Monongalia County, West Virginia.

1. Initial Essure[®] Procedure:

501. Upon information and belief, sometime in or around July 2012, Plaintiff Daugherty underwent the Essure[®] procedure under general anesthesia at Uniontown Hospital in Uniontown, Pennsylvania.

502. Daniel Nahhas, MD implanted the Essure[®] device in Plaintiff Daugherty.

503. Further, Plaintiff Daugherty was not informed that the Essure[®] procedure as marketed was not intended to take place under general anesthesia and that the balance of risks and benefits of Essure[®] versus tubal ligation was unfavorable to Essure[®] under such circumstances.

504. Plaintiff Daugherty was directed toward Essure[®] by her providers. It was her understanding that Essure[®] was the safest form of sterilization available.

2. Post Essure[®] Procedure Condition and Treatment:

505. Plaintiff Daugherty's post-procedure course has been marked by increasingly severe pain and discomfort, including, but not limited to, heavy and irregular menstrual cycles, abdominal pain, excessive bloating, dental issues, rashes, joint pain, severe migraines, chronic bacterial vaginosis, chronic fatigue, dizziness, memory loss and a metallic taste in her mouth. Before Essure[®], she had not experienced this combination of symptoms, and she had no problem going about her daily life.

506. Since undergoing the Essure[®] procedure, Plaintiff Daugherty has repeatedly sought treatment for her symptoms, but none of her treating physicians were able to determine their cause.

507. Plaintiff Daugherty still has the Essure[®] device surgically implanted.

508. Plaintiff Daugherty is unable to wear fake or “costume” jewelry which often contain nickel due to skin irritation.

509. Plaintiff Daugherty did not realize that she had a legal remedy due to her injuries from Essure[®] until she saw a legal advertisement, sometime on or about August 19, 2016, describing symptoms like hers which were also being experienced by thousands of other women who had been implanted with the Essure[®] device. It was at this time that she truly understood that her symptoms were related to Essure[®] and the legal options available to her.

G. CRYSTAL ADAMS

510. Plaintiff Adams is thirty-six (36) years old and resides in Indianapolis, Marion County, Indiana.

1. Initial Essure[®] Procedure:

511. On or around August 20, 2013, Plaintiff Adams underwent the Essure[®] procedure (ESS305, Lot #50713475) at Obstetrics & Gynecology of Indiana (“OB/GYN”) in Indianapolis, Marion County, Indiana.

512. Tara Debikey, MD, implanted the Essure[®] device in Plaintiff Adams.

513. It was Plaintiff Adams’ understanding that Essure[®] implantation was a less complex procedure, did not require an incision, and was as safe or safer than a bilateral tubal ligation.

2. Post Essure[®] Procedure Condition and Treatment:

514. Plaintiff Adams underwent a HSG exam on or about January 8, 2014 which noted “bilateral tubal occlusion and satisfactory location of [the] micro inserts.”

515. Plaintiff Adams' post-procedure course has been marked by severe and constant abdominal/pelvic pain, pain after intercourse, extreme fatigue and brittle teeth. She never experienced such immense abdominal/pelvic pain prior to undergoing the Essure[®] procedure.

516. On or around November 13, 2017, Plaintiff Adams presented to OB/GYN with complaints of pelvic pressure and pain. A transvaginal pelvic ultrasound revealed fluid within the endometrium and the Essure[®] coils appeared in place. She was assessed with pelvic inflammatory disease.

517. Plaintiff Adams returned to OB/GYN for a follow up visit on or about November 16, 2017. She reported no significant change since her last office visit and had complaints of nausea, abdominal pain, back pain and extreme fatigue. She was admitted to Franciscan Health for in-patient treatment and observation.

518. Plaintiff Adams underwent a CT scan of her abdomen and pelvis on or about November 17, 2017, which noted "[n]o acute diagnostic abnormality of the abdomen or pelvis."

519. Plaintiff Adams was discharged from Franciscan Health on or about November 18, 2017, with a diagnosis of pelvic inflammatory disease. Upon discharge, she continued to report lower/upper abdominal pain.

520. On or around November 29, 2017, Plaintiff Adams presented to OB/GYN with continued complaints of abdominal pain, nausea and chest discomfort. She was assessed with pelvic pain.

521. Plaintiff Adams underwent an operative laparoscopy with bilateral salpingectomy, Essure[®] coil removal and left ovarian cystectomy on or about December 20, 2017, performed by James Wisler, Jr., MD, at Community Surgery Center South in Indianapolis, Indiana. The postoperative diagnoses included "[d]yspareunia, Essure pelvic pain, Essure coil pain syndrome [and] [l]eft ovarian cyst."

522. During her post-operative visit on or about January 25, 2018, Plaintiff Adams reported some incisional pain but was otherwise feeling fine following her surgery.

523. Plaintiff Adams has not been tested for a nickel allergy but cannot wear “fake” or “costume” jewelry which often contain nickel due to skin irritation.

524. Since the removal of the device, Plaintiff Adams’ symptomatology has completely resolved. Until the removal, neither she nor her doctors could clearly correlate her problems as being associated with the device. After the removal, the cause of her problems became obvious due to their resolution.

H. LILYBETT MARTIR

525. Plaintiff Martir is forty-one (41) years old and resides in Belleville, Essex County, New Jersey.

1. Initial Essure® Procedure:

526. Upon information and belief, on or around November 17, 2010, Plaintiff Martir underwent the Essure® procedure under general anesthesia at Clara Mass Medical Center in Belleville, New Jersey.

527. Michael Straker, MD implanted the Essure® device in Plaintiff Martir.

528. Further, Plaintiff Martir was not informed that the Essure® procedure as marketed was not intended to take place under general anesthesia and that the balance of risks and benefits of Essure® versus tubal ligation was unfavorable to Essure® under such circumstances.

529. Plaintiff Martir was directed toward Essure® by her providers. It was her understanding that Essure® was pain free and safer than a traditional tubal ligation.

2. Post Essure® Procedure Condition and Treatment:

530. Plaintiff Martir’s post-procedure course has been marked by severe pain and discomfort, including, but not limited to, irregular and heavy menstrual periods, pelvic pain,

weight gain, bloating, chronic fatigue, joint pain, hair loss, severe migraines, a metallic taste in her mouth, and dental issues. Before Essure®, she had not experienced this combination of symptoms and had no problem going about her daily life.

531. Since undergoing the Essure® procedure, Plaintiff Martir repeatedly sought treatment for her symptoms in Belleville, New Jersey.

532. Upon information and belief, sometime in or around April 2017, Plaintiff Martir complained to Dr. Straker about her continued pelvic pain and irregular cycle. Dr. Straker recommended that she undergo a hysterectomy to treat her symptoms.

533. On or about May 22, 2017, Plaintiff Martir underwent a hysterectomy with bilateral salpingectomy to remove the Essure® device which was performed by Dr. Straker at Clara Mass Medical Center in Belleville, New Jersey.

534. Despite suffering from these symptoms for over six years, Plaintiff Martir's symptoms largely resolved only after removal of her Essure® device. Until the removal, neither she nor her doctors could clearly correlate her problems as being associated with the device. After the removal, the cause of her symptoms became obvious due to their resolution.

I. MARIE COLLINS HUGHES

535. Plaintiff Collins Hughes is thirty-five (35) years old and resides in Wynne, Cross County, Arkansas.

1. Initial Essure® Procedure:

536. On or around April 5, 2013, Plaintiff Collins Hughes underwent the Essure® procedure at the office of Brandy A. Davis, MD in Forrest City, St. Francis County, Arkansas.

537. Brandy Davis, MD implanted the Essure® device in Plaintiff Collins Hughes.

2. Post Essure® Procedure Condition and Treatment:

538. Plaintiff Collins Hughes' post-procedure course has been marked by menorrhagia, dyspareunia, pelvic/abdominal pain, joint pain and significant weight gain. Before Essure®, Plaintiff's menstrual periods were not as heavy, nor did they last as long, and she had no problem with going about her daily life.

539. On or around January 25, 2017, Plaintiff Collins Hughes presented to Wynne Medical Clinic, PA in Wynne, Arkansas with complaints of pelvic and lower abdominal pain. She further related a history of having the Essure® procedure over one year prior to the visit, having asked Dr. Davis to remove the devices, and Dr. Davis declining to do so. She requested a referral from Dr. Beaton to have the devices removed on this visit. She was assessed with female pelvic pain and a urinary tract infect and was referred for a surgical consult.

540. On or about February 8, 2017, Plaintiff Collins Hughes presented to Women's Clinic of Forrest City ("WC") for a surgical consult. She reported complaints of severe dyspareunia and chronic pelvic pain since Essure® placement. Dr. Cem Sarinoglu performed a transvaginal ultrasound before ultimately assessing "[s]evere dyspareunia and chronic pelvic pain secondary to Essure procedure."

541. Plaintiff Collins Hughes also experienced swelling over her pelvic area following her Essure® implant procedure.

542. While Plaintiff Collins Hughes has never been diagnosed with a nickel allergy, she is unable to wear costume jewelry, which often contains nickel, because it causes her skin to break out in a rash, with itching and swelling at the site of contact.

543. Plaintiff Collins Hughes underwent a laparoscopic removal of the Essure® device on or about February 27, 2017, performed by Dr. Sarinoglu at Forrest City Medical Center. The operative report noted the "bilateral Essure device were completely removed [extracted] from the

tubes.” The pathology report further noted “[p]ortions of soft tissue show scar, hemosiderin and focal calcification.”

544. On or around March 6, 2017, Plaintiff Collins Hughes presented to WC for a post-surgical follow up with Dr. Sarinoglu. She reported that she was in “excellent health today with no complaints.”

545. Plaintiff Collins Hughes’ symptoms largely resolved only after removal of the Essure® device. Until the removal, neither she nor her doctors could clearly correlate her problems as being associated with the device. After the removal, the cause of her problems became obvious due to their resolution.

J. MARSHA CREASEY

546. Plaintiff Creasey is thirty-two (32) years old and resides in Lexa, Phillips County, Arkansas.

1. Initial Essure® Procedure:

547. On or around February 10, 2014 Plaintiff Creasey underwent the Essure® procedure at The Women’s Health Clinic of Forrest City, St. Francis County, Arkansas.

548. Cem Sarinoglu, MD implanted the Essure® device in Plaintiff Creasey.

2. Post Essure® Procedure Condition and Treatment:

549. Plaintiff Creasey’s post-procedure has been marked by severe dysmenorrhea and menometrorrhagia, abdominal pain, a perforated right ovary, fallopian tube infections, extreme fatigue, headaches and weight fluctuation. Before Essure®, Plaintiff had not experienced this combination of symptoms. Her menstrual cycles were normal and she had no problem going about her daily life.

550. For the next several years following the Essure® procedure, Plaintiff Creasey repeatedly sought treatment for her symptoms but no physician could determine their cause.

551. For example, on or around December 26, 2015, Plaintiff Creasey presented to the emergency room at Helena Regional Medical Center (“HRMC”) in Helena, Arkansas for complaints of pelvic pain, neck pain and chest pressure. She underwent a CT scan which showed a ruptured ovarian cyst and a sonogram which showed a right adnexal complex mass. Based on the radiology reports, she underwent a laparoscopic right oophorectomy, lysis of adhesions and evacuation of hemoperitoneum performed by Dr. Mak Ernest. The operative report further noted a “Left Essure sub serosal perforation.”

552. On or around January 11, 2016, Plaintiff Creasey presented to the emergency department at HRMC with complaints of left lower quadrant abdominal pain. She underwent a transabdominal pelvic ultrasound which “suspect[ed] . . . bilateral Essure devices in place.” She was assessed with a urinary tract infection.

553. On or around July 15, 2016, Plaintiff Creasey presented to HRMC with complaints of abdominal pain, fever and vaginal discharge. She underwent another transabdominal pelvic ultrasound and noted the bilateral Essure® devices appear “adequately implanted.” She was diagnosed with salpingitis and hospitalized for five days.

554. Plaintiff Creasey continues to suffer from injuries, including but not limited to pain and cramping cause by the implantation of the Essure® device. She has sought removal of the remaining Essure® coil however, her treating physician has not recommended surgery at this time because of the amount of abdominal scar tissue.

555. Sometime in or around August 2016, Plaintiff Creasey saw a legal advertisement describing a potential action to be filed against the manufacturers of the Essure® device. It was not until seeing this advertisement that Plaintiff could reasonably have concluded that there is a causal relationship between her post-Essure® implantation symptomatology, a defect in the Essure® device, or any wrongdoing on the part of the manufacturer of the Essure® device.

K. AMBER HEDGES

556. Plaintiff Hedges is thirty-seven (37) years old and resides in Malvern, Hot Spring County, Arkansas.

1. Initial Essure® Procedure:

557. On or around April 5, 2007, Plaintiff Hedges underwent the Essure® procedure under general anesthesia at National Park Medical Center in Hot Springs, Arkansas.

558. Leo Yang, MD implanted the Essure® device in Plaintiff Hedges.

559. Plaintiff Hedges was not informed that the Essure® procedure as marketed was not intended to take place under general anesthesia and that the balance of risks and benefits of Essure® versus tubal ligation was unfavorable to Essure® under such circumstances.

2. Post Essure® Procedure Condition and Treatment:

560. Plaintiff Hedges' post-procedure course has been marked by heavy abnormal bleeding, pelvic pain and fatigue.

561. Plaintiff Hedges presented to Central Arkansas Women's Group on or around September 26, 2016, with complaints of pelvic pain and irregular menses. She underwent a transvaginal ultrasound which revealed two cysts on her left ovary. She was assessed with abnormal uterine bleeding and pelvic pain.

562. On or around December 29, 2016, Plaintiff Hedges underwent a vaginal hysterectomy with bilateral salpingectomy and a left oophorectomy performed by Dr. David Caldwell at Saline Memorial Hospital ("SMH") in Benton, Arkansas due to her dysfunctional uterine bleeding, pelvic pain and left ovarian mass.

563. Unfortunately, Plaintiff Hedges suffered complications following her surgery and, on or about January 9, 2017, she underwent a vaginal cuff revision due to a pelvic hematoma performed by Dr. Caldwell at SMH.

564. Since the removal of the device, Plaintiff Hedges' symptomatology has completely resolved. Until the removal, neither she nor her doctors could clearly correlate her problems as being associated with the device. After the removal, the cause of her problems became obvious due to their resolution.

L. MARY POWELL

565. Plaintiff Powell is thirty (30) years old and resides in Emmet, Nevada County, Arkansas.

1. Initial Essure® Procedure:

566. On or around November 4, 2015, Plaintiff Powell underwent the Essure® procedure at Baptist Health Women's Clinic ("BHWC") in Arkadelphia, Arkansas.

567. Alexis McCollum, MD implanted the Essure® device in Plaintiff Powell.

2. Post Essure® Procedure Condition and Treatment:

568. Plaintiff Powell's post-procedure course has been marked by heavy, abnormal uterine bleeding, dyspareunia and pelvic pain. Plaintiff Powell also experiences severe headaches which she never experienced prior to the implant.

569. On or about March 17, 2016, Plaintiff Powell underwent a HSG exam which demonstrated bilateral tubal occlusion.

570. On or about November 30, 2016, Plaintiff Powell presented to BHWC with complaints of irregular, heavy menses and dyspareunia. She underwent a transvaginal ultrasound which noted the "Essure implants . . . appear in proper location." She was assessed with abnormal uterine and vaginal bleeding.

571. Plaintiff Powell also sought treatment for severe headaches from Wadley Rural Health Clinic. She underwent testing to determine the cause of the headaches that have developed

since the implant, but she was not provided any clear answer. She is now on medication to treat these headaches.

572. Plaintiff Powell presented to Collom & Carney Clinic in Texarkana, Texas on or about November 10, 2017, with complaints of chronic pelvic pain, irregular bleeding, and dyspareunia. She underwent a transvaginal ultrasound which noted the left Essure[®] coil appeared to be in proper position but the “right coil is probably malposition[ed].” The plan was to proceed with a laparoscopic vaginal hysterectomy with bilateral salpingectomy.

573. Plaintiff Powell underwent a robotic hysterectomy with bilateral salpingectomy and cystoscopy on or about February 22, 2018 performed by Dr. Sudheer Jayaprabhu at Wadley Regional Medical Center due to her continued pelvic pain, dysfunctional uterine bleeding and postcoital bleeding. The pathology report noted “Essure coils in situ.”

574. During her post-operative visit on or about March 19, 2018, Plaintiff Powell reported no complaints following the removal of the Essure[®] device.

575. Since the removal of the Essure[®] device, Plaintiff Powell’s symptomatology has completely resolved. Until the removal, neither she nor her doctors could clearly correlate her problems as being associated with the device. After the removal, the cause of her problems became obvious due to their resolution.

M. KATHERINE LUCERO

576. Plaintiff Lucero is twenty-four (24) years old and resides in Denver, Denver County, Colorado.

1. Initial Essure[®] Procedure:

577. On or around September 2, 2015, Plaintiff Lucero, who was only 21 years old at the time, underwent the Essure[®] procedure (ESS305, Lot #C51079) at the offices of Michael L. Hall, PC in Englewood, Colorado.

578. Michael Hall, MD, implanted the Essure[®] device in Plaintiff Lucero.

579. Plaintiff Lucero was directed toward Essure[®] by her providers. Dr. Hall described the Essure[®] implantation as a less complex procedure, did not require an incision, and was as safe or safer than a bilateral tubal ligation.

2. Post Essure[®] Procedure Condition and Treatment:

580. Plaintiff Lucero's post-procedure course has been marked by menometrorrhagia, amenorrhea, chronic pelvic/abdominal pain, abnormal water retention, hematometra, body aches, weight gain, joint pain, fatigue and a subsequent pregnancy. Before Essure[®], Plaintiff's menstrual periods were not nearly as heavy, nor did they last as long, and she had no problem with going about her daily life.

581. Approximately over one month after the implant procedure, Plaintiff Lucero presented to Dr. Hall on or about October 5, 2015 with complaints of constant bleeding since the Essure[®] implant procedure. She was given a Depo-Provera injection.

582. On or about November 17, 2015, Plaintiff Lucero presented to the emergency department at St. Anthony Hospital North ("SAHN") complaining of pelvic pain for the past three months, joint pain and difficulty breathing. A transvaginal ultrasound noted increased endometrial fluid and debris in the endometrial canal. She was diagnosed with pelvic pain and prescribed pain medication.

583. Plaintiff Lucero returned to Dr. Hall on or about November 20, 2015, as a follow up to her emergency room visit. Dr. Hall performed a dilation and curettage procedure due to the fluid accumulation and an obstruction in the cervical opening. The procedure note indicated a "significant amount of blood [was] removed [and a] mild amount of mucous [was] pulled out of [the] cervix."

584. Plaintiff Lucero returned to the emergency department at SAHN on or about December 21, 2015 reporting one week of generalized weakness, body aches, vision problems, dysuria, vomiting, headaches and abdominal pain. An abdominal ultrasound was negative. Her symptoms were noted to be intermittent over the past three months and their etiology was unclear. She was diagnosed with nausea and vomiting, leukocytosis and hyperbilirubinemia, and advised to follow up with her gynecologist.

585. Plaintiff Lucero presented to the emergency department at SAHN on or about February 28, 2016, and again on May 2, 2016, with similar but worsening complaints of chronic abdominal/pelvic pain as she had been experiencing in the months before, and “heavy” vaginal bleeding. By May 2, 2016, her abdominal pain was occurring almost daily. Despite repeated diagnostic tests, her physicians were unable to determine the etiology of her symptoms.

586. Plaintiff Lucero discovered that she was pregnant sometime in or around January or February 2017. She delivered her daughter on July 9, 2017.

587. On or about October 31, 2017, Plaintiff Lucero underwent a laparoscopic hysterectomy total abdominal with bilateral salpingectomy due to her chronic pelvic pain and absence of left Essure® coil noted on prior ultrasound performed by Dr. Bhavani Chillara at SAHN. The operative report notes “the [right] Essure coil seen which was held and removed from the cornual of [the] Uterus [and] [n]o Essure coil [was] found on the left side in the cavity or in the tube.” The report further noted that “[t]o the extent possible, abdominal cavity was one more time explored to see if potentially the Essure coil was displaced into the abdominal/peritoneal cavity but no evidence seen.”

588. Plaintiff Lucero was never informed that Essure® was not an appropriate form of birth control for such a young woman, as her opinion about sterilization may change, leaving her

with regret; and because it is typical for young women to experience problems with their menstrual cycles, which are treated with hormonal birth control but cannot be treated with Essure®.

589. Plaintiff Lucero has not been tested for a nickel allergy, but she cannot wear “fake” or “costume” jewelry which often contain nickel due to skin irritation.

590. Sometime in or around February 2017, Plaintiff Lucero was forwarded and saw a legal advertisement describing a potential action to be filed against the manufacturers of the Essure® device. It was not until seeing this advertisement that Plaintiff could reasonably have concluded that there is a causal relationship between her post-Essure® implantation symptomatology, a defect in the Essure® device, or any wrongdoing on the part of the manufacturer of the Essure® device.

N. TYNISHA ELLISON

591. Plaintiff Ellison is thirty-six (36) years old and resides in Washington, District of Columbia.

1. Initial Essure® Procedure:

592. On or around November 24, 2008, Plaintiff Ellison underwent the Essure® procedure (ESS305, Lot #627437) under general anesthesia at United Medical Center in Washington, D.C.

593. Christopher Warner, MD, implanted the Essure® device in Plaintiff Ellison.

594. Further, Plaintiff Ellison was not informed that the Essure® procedure as marketed was not intended to take place under general anesthesia and that the balance of risks and benefits of Essure® versus tubal ligation was unfavorable to Essure® under such circumstances.

2. Post Essure® Procedure Condition and Treatment:

595. On or around March 25, 2009, Plaintiff Ellison underwent a HSG exam which showed “[s]uccessful tubal sterilization bilaterally.”

596. Plaintiff Ellison's post-procedure course has been marked by dysmenorrhea, vaginal irritation and infections, urinary tract infections, heavy menstrual bleeding, pelvic pain and urinary frequency. Prior to Essure[®], her menstrual cycle was normal, and she had no problem with going about her daily life.

597. Over the next three years, Plaintiff Ellison reported complaints to Dr. Warner about irregular menstrual cycles when not on Depo-Provera, and pelvic pain. For example, on or around November 29, 2012, she reported to Dr. Warner that the pelvic pain was worsening and would "stop her in her tracks." A transvaginal sonogram was performed showing a left ovarian cyst.

598. On or around February 28, 2014, Plaintiff Ellison underwent a hysteroscopy, dilation and curettage (D&C) and ablation performed by Dr. Warner at the Washington Wellness Institute to address her persistent menorrhagia.

599. On or about November 18, 2015, Plaintiff Ellison underwent a transabdominal and endovaginal ultrasound at Georgetown University Hospital which noted "tiny myometrial cysts [were] suggestive of adenomyosis."

600. Additionally, Plaintiff Ellison suffered from migraine headaches following her Essure[®] implant. She underwent an MRI of the brain on or around September 23, 2016, which was unremarkable.

601. On or about August 22, 2017, Plaintiff Ellison underwent a laparoscopic bilateral salpingectomy with Essure[®] removal, diagnostic hysteroscopy and D&C performed by Dr. John Buck at MedStar Washington Hospital Center due to her continued pelvic pain. The operative report noted the Essure[®] device was removed "completely on the right side at time of salpingectomy [and] [r]emoved partially on the left side. Diagnostic hysteroscopy unable to visualize remaining partial Essure in left cornua. Novasure not performed due to retained Essure and risk of thermal spread."

602. Plaintiff Ellison continues to suffer from her injuries as a result of her Essure[®] implantation, and in all likelihood, will need a total hysterectomy to address her symptomatology and to remove the retained portion of the left-sided Essure[®] device.

603. Plaintiff Ellison did not realize that she had a legal remedy due to her injuries from Essure[®] until she saw a legal advertisement on social media describing symptoms like hers which were also being experienced and suffered by thousands of other women who had been implanted with the Essure[®] device. It was at this time that she truly understood that her symptoms were related to Essure[®] and the legal options available to her.

O. ANGELIQUE ABDUL-MATIN

604. Plaintiff Abdul-Matin is forty-six (46) years old and resides in Duluth, Gwinnett County, Georgia.

1. Initial Essure[®] Procedure:

605. In or around 2010, Plaintiff Abdul-Matin underwent the Essure[®] procedure (ESS305, Lot #646522) at Orlando Health Physician Associates in Edgewood, Orange County, Florida.

606. Ricardo Lopez, M.D., implanted the Essure[®] device in Plaintiff Abdul-Matin.

607. Plaintiff Abdul-Matin was directed toward Essure[®] because it was a simple, in-office procedure. She was assured that Essure[®] was as safe as or safer than tubal ligation.

2. Post Essure[®] Procedure Condition and Treatment:

608. Plaintiff Abdul-Matin's post-procedure period has been marked by excruciating pelvic pain, painful intercourse, extreme fatigue, anemia, migraines, low back pain and menometrorrhagia.

609. On or around January 4, 2013, Plaintiff Abdul-Matin presented at Kaiser Permanente in Duluth, Georgia for right-sided pelvic and abdominal pain that had been occurring

for the past one to two months and some dysuria with gross hematuria. She was diagnosed with right lower quadrant abdominal pain, UTI, and menorrhagia.

610. On or around January 5, 2013, and January 8, 2013, CT scans with and without contrast of Plaintiff Abdul-Matin's abdomen and pelvis were performed. The CT scan showed a right adnexal cyst, likely ovarian and an enlarged uterus "suggesting fibroids." The Essure® devices were noted to be located in the pelvis.

611. On or around February 4, 2013, in response to the CT scan results, Plaintiff Abdul-Matin underwent an ultrasound of her pelvis. The ultrasound revealed that the pelvis was diffusely enlarged with bulky uterine fibroids. It was also noted that the Essure® implant was noted in the right uterine cornua region and that it may have "migrated proximally from the right fallopian tube and may no longer be functional."

612. Plaintiff Abdul-Matin followed up at Kaiser Permanente on or around February 22, 2013. She reported lower abdominal pain that was becoming worse throughout the month and her menses had been getting heavier for the past six to eight months. She further explained that she was using tampons and pads together and changing them multiple times a day. She was diagnosed with menorrhagia, leiomyoma of the uterus and pelvic pain. Iron therapy was prescribed.

613. On or around August 25, 2014, Plaintiff Abdul-Matin reported menorrhagia, pelvic pain and pressure to her physician at Kaiser Permanente. The MRI of her pelvis showed a fibroid uterus and a few small Nabothian cysts in the cervix. Bilateral Essure® devices were noted on MRI.

614. On or around January 20, 2017, Plaintiff Abdul-Matin returned to Kaiser Permanente for her menorrhagia and pelvic pain and stated she was ready for surgical intervention.

615. On or around April 6, 2017, Plaintiff Abdul-Matin underwent a total abdominal hysterectomy with bilateral salpingectomy performed by Dr. Michelle Covalt at Northside

Hospital in Atlanta, Georgia. The pathology report noted the left Essure[®] device was located in the left fallopian tube and a portion of the right Essure[®] device was present in the right cornu and did not “appear to extend into the right fallopian tube.”

616. After the removal of the Essure[®] device, Plaintiff Abdul-Matin’s symptoms resolved. Until the removal, neither she nor her doctors could clearly correlate her problems as being associated with the device. After the removal, the cause of her problems became obvious due to their resolution.

P. STEPHANIE FERNANDEZ

617. Plaintiff Fernandez is thirty-six (36) years old and resides in Sanford, Seminole County, Florida.

1. Initial Essure[®] Procedure:

618. On or around June 4, 2010, Plaintiff Fernandez underwent the Essure[®] procedure (ESS305, Lot #708871) upon information and belief, at South Seminole Hospital in Longwood, Seminole County, Florida.

619. Dr. Jose López-Cintrón, MD implanted the Essure[®] in Plaintiff Fernandez.

620. Plaintiff Fernandez was directed toward Essure[®] by her providers. Plaintiff was told that it was a less invasive procedure, it was as safe or safer than a bilateral tubal ligation and there was no downtime following the Essure[®] procedure.

2. Post Essure[®] Procedure Condition and Treatment:

621. Plaintiff Fernandez’s post-procedure course has been marked by migration of the Essure[®] device, removal of one Essure[®] device, menorrhagia, dysmenorrhea, extreme fatigue, decreased libido and weight gain and loss. Before Essure[®], Plaintiff’s menstrual periods were not nearly as heavy, nor did they last as long, and she had no problem with going about her daily life.

622. On or around October 25, 2010, Plaintiff Fernandez presented to Dr. López-Cintrón to discuss the results of her HSG exam which was positive for spillage and no blockage. It also showed that the “[r]ight (coil) in but [l]eft (coil) not”.

623. On or around December 13, 2010, Plaintiff Fernandez underwent a diagnostic hysteroscopy at the office of Dr. López-Cintrón to determine the location of the left-sided Essure[®] device. Dr. López-Cintrón was able to locate the Essure[®] coil outside of the left fallopian tube in the uterus and then utilized forceps to pull the coil out of Plaintiff’s uterus through her fallopian tube.

624. On or around December 17, 2010, Plaintiff Fernandez underwent a laparoscopic bilateral tubal ligation with filshie clips at South Seminole Hospital due to the migration of the left Essure[®] coil. The right Essure[®] coil was not removed during this procedure.

625. Plaintiff Fernandez’s symptomatology developed gradually in the months and years following the implant of the Essure[®] device.

626. On or around August 31, 2011, Plaintiff Fernandez complained to Dr. López-Cintrón about her heavy, long periods that she was experiencing. She was assessed with abnormal uterine bleeding and prescribed Lysteda.

627. By January of 2013, Plaintiff Fernandez had experienced menorrhagia and decreased libido, which she reported to Dr. Normal Lamberty.

628. On or around January 16, 2013, Plaintiff Fernandez underwent a transvaginal ultrasound at Physician Associates – Longwood for her pelvic pain and dysmenorrhea. The ultrasound report was normal. During her follow-up appointment with Dr. Lamberty on January 29, 2013, she was prescribed, Lysteda, an oral contraceptive to help manage her symptoms.

629. On or around April 15, 2014, Plaintiff Fernandez presented to Dr. Lamberty and related a history of irregular, heavy menses. She subsequently underwent a transvaginal

ultrasound. The ultrasound showed a right functional ovarian cyst and noted the right Essure[®] coil. She was diagnosed with irregular menstrual bleeding and prescribed Lysteda to control her symptoms. Over the next several months, Plaintiff Fernandez continued to complain to Dr. López-Cintrón about her menorrhagia, dysmenorrhea and weight gain. She was prescribed oral contraceptives and Adipex for weight loss and to control her ongoing symptoms.

630. On or about December 1, 2016, Plaintiff Fernandez presented to Dr. Edward Magee and reported being able to feel the remaining Essure[®] device about two weeks prior to the beginning of her menses. The sensation was described as painful. Dr. Magee referred her for a surgical consult to Dr. Michele Cofield and possible removal of the Essure[®] device.

631. In or around March/April of 2018, Plaintiff Fernandez began treating with Heathrow OBGYN where she underwent an ultrasound that showed a cyst on her fallopian tube. The Plaintiff has now been referred to another OBGYN for possible removal of the remaining coil.

632. Plaintiff Fernandez underwent a second HSG exam sometime in or around July 2018 which noted spillage and possible migration of the right coil. She is continuing to seek possible removal of the remaining coil.

633. Plaintiff Fernandez is unaware if she has a nickel allergy, but she is unable to wear “costume” jewelry as it causes skin irritation.

634. At no time has a physician or medical professional indicated to Plaintiff Fernandez that there is a causal relationship between her post-Essure[®] implantation symptomatology, a defect in the Essure[®] device, or any wrongdoing on the part of the manufacturer of the Essure[®] device.

635. In or around May 2017, Plaintiff Fernandez saw a legal advertisement describing a potential action to be filed against the manufacturers of the Essure[®] device. It was not until seeing this advertisement that she could reasonably have concluded that there is a causal relationship

between her post-Essure[®] implantation symptomatology, a defect in the Essure[®] device, or any wrongdoing on the part of the manufacturer of the Essure[®] device.

Q. TRESSA SHIELDS

636. Plaintiff Shields is forty-seven (47) years old and resides in Lithia, Douglas County, Georgia.

1. Initial Essure[®] Procedure:

637. On or around September 16, 2009, Plaintiff Shields underwent the Essure[®] procedure at North Florida OB/GYN Associates, P.A., in Orange Park, Clay County, Florida.

638. Arjav A. Shah, MD, implanted the Essure[®] device in Plaintiff Shields.

2. Post Essure[®] Procedure Condition and Treatment:

639. Plaintiff Shields underwent a HSG on or about December 9, 2009, which revealed that the right coil was located adjacent to the proximal right fallopian tube with tubal patency bilaterally. Plaintiff Shields was advised to continue oral contraceptives and repeat her HSG in three months.

640. Plaintiff Shields' post-procedure course has been marked by abdominal and pelvic pain radiating into back. Before Essure[®], Plaintiff Shields had not experienced this combination of symptoms while not on birth control. Her menstrual periods were normal and she had no problem with going about her daily life.

641. On or around January 18, 2010, Plaintiff Shields presented Dr. Shah with complaints of amenorrhea. Plaintiff Shields complained that she had no menses since the Essure[®] procedure. Dr. Shah gave Plaintiff Shields some samples of Loestrin 24 and requested she follow up in two months.

642. On or around February 3, 2010, Plaintiff Shields presented Dr. Shah with complaints of abdominal/pelvic pain that radiates to center of back since Essure[®] surgery. Dr. Shah ordered an ultrasound.

643. On or around February 15, 2010, Plaintiff Shields followed up with Dr. Shah with present complaints of abdominal/pelvic pain and for the results of the ultrasound. Dr. Shah noted that the sonogram was normal. Dr. Shah requested that Plaintiff Shields undergo physical rehab for back disease.

644. Plaintiff Shields underwent another HSG on or about March 15, 2010, which showed the right coil was adjacent to the fallopian tube. There was normal-appearing patent right fallopian tube. The left coil was noted to be in good position, with backflow of contrast into the adjacent interstitium from the proximal isthmic portion of the tube, but the remainder the tube was not opacified and was therefore felt to be occluded.

645. On or around April 13, 2010, Plaintiff Shields presented Dr. Shah with complaints of back pain and right-side pain. She also noted that the Essure[®] device was not properly implanted on her right side.

646. On or around July 12, 2010, Plaintiff Shields underwent a Laparoscopy with Tubal Ligation performed by Dr. Shah at the Fleming Island Surgery Center. The operative report notes that "Filshie clips" were placed. It does not reflect removal of the fallopian tubes or Essure[®] devices.

647. To date, Plaintiff Shields is unaware as to whether or not her Essure[®] was removed and is currently seeking confirmation to determine whether the device remains in her body.

R. MAIDA URIBE

648. Plaintiff Uribe is forty-three (43) years old and resides in Belvidere, Boone County, Illinois.

1. Initial Essure® Procedure:

649. On or around January 7, 2009, Plaintiff Uribe underwent the Essure® procedure (ESS205, Lot #624485) at SwedishAmerican Hospital (“SAH”) in Rockford, Illinois.

650. Mohamad Mahmoud, MD, implanted the Essure® device in Plaintiff Uribe.

651. Plaintiff Uribe was directed toward Essure® by her providers. It was her understanding that Essure® implantation was a less complex procedure, did not require an incision, and was as safe or safer than a bilateral tubal ligation.

2. Post Essure® Procedure Condition and Treatment:

652. Plaintiff Uribe’s post-procedure course has been marked by severe and constant abdominal/pelvic pain and included menometrorrhagia, dyspareunia, headaches, urinary tract infections, chronic joint pain and various rashes. She never experienced such immense abdominal and joint pain prior to undergoing the Essure® procedure.

653. On or around April 1, 2009, Plaintiff Uribe underwent a HSG exam which showed occlusion of the right fallopian tube; however, the left fallopian tube was patent and noted “the left Essure tubal occlusive device is curled in the left mid pelvis.”

654. Due to the failed left Essure® device, on or about May 27, 2009, Plaintiff Uribe underwent an exploratory laparoscopy, lysis of pelvic adhesions, retrieval of the left Essure® device, left salpingectomy, and chromopertubation performed by Dr. Mahmoud at SAH. The operative report noted the “[l]eft Essure device curled under the serosal of the left cornu.”

655. A few months later, on or around October 4, 2009, Plaintiff Uribe presented to the emergency department at SAH with complaints of joint pain and swelling, and generalized weakness. The notes reflect that “her bilateral presentation of pain and swelling is most consistent with generalized inflammatory process or autoimmune disease.” Her assessments included joint pain. She was subsequently seen by a rheumatologist her diagnosed with rheumatoid arthritis.

656. For the next several years, Plaintiff Uribe continued to seek treatment for complaints of chronic abdominal and joint pain, back pain, headaches and various rashes. Unfortunately, her physicians were not able find the cause of her symptoms, as they persisted despite constant treatment and medicinal therapy.

657. For example, on or about December 26, 2010, Plaintiff Uribe presented to the emergency department at SAH reporting right upper quadrant pain for the past three days. A CT scan reported a right ovarian cyst and the “bilateral fallopian tube essure coiled are noted.” She was assessed with abdominal pain and prescribed pain medication.

658. Plaintiff Uribe again presented to SAH on or about May 27, 2012, with complaints of abdominal and flank pain. An x-ray noted the “Essure tubes in the pelvis” but was otherwise unremarkable. She was assessed with gastritis.

659. Due to complaints of dyspareunia, Plaintiff Uribe underwent a transvaginal/pelvis ultrasound on or about May 16, 2014, which showed a “[l]inear echogenic focus in the right cornua most likely component of tubal occlusive device” and a small left ovarian cyst.

660. Plaintiff Uribe has suffered from these symptoms for over nine (9) years and still has the right Essure® device surgically implanted.

661. Plaintiff Uribe is unable to wear fake or “costume” jewelry which often contain nickel due to skin irritation.

662. Plaintiff Uribe did not realize that she had a legal remedy due to her injuries from Essure® until she saw a legal advertisement describing symptoms like hers which were also being experienced and suffered by thousands of other women who had been implanted with the Essure® device. It was at this time that she truly understood that her symptoms were related to Essure® and the legal options available to her.

S. JOY ANNA EDGE

663. Plaintiff Edge is thirty-five (35) years old and resides in Kenyon, Goodhue County, Minnesota.

1. Initial Essure® Procedure:

664. On or around June 24, 2010, Plaintiff Edge underwent the Essure® procedure (ESS305, Lot #713453) under general anesthesia at the Olmsted Medical Center in Rochester, Minnesota. Dr. Kimberly McKeon performed the implant of the Essure® on Plaintiff Edge.

665. Further, Plaintiff Edge was not informed that the Essure® procedure as marketed was not intended to take place under general anesthesia and that the balance of risks and benefits of Essure® versus tubal ligation was unfavorable to Essure® under such circumstances.

666. Plaintiff Edge was directed toward Essure® by her providers. Plaintiff was told that it was a less invasive procedure than a bilateral tubal ligation and that it was permanent.

2. Post Essure® Procedure Condition and Treatment:

667. Plaintiff Edge's post-procedure course has been marked by irregular menses, dysmenorrhea, mild cramping, spotting, heavy menstrual bleeding, bilateral abdominal cramping, vaginal discharge, dyspareunia, allergic reactions, tooth pain and loss, joint pain and headaches. Before Essure®, her menstrual periods were not nearly as heavy, nor did they last as long, and she had no problem with going about her daily life.

668. Plaintiff Edge had a HSG exam on September 20, 2010. The findings were unremarkable, and occlusion was viewed in both fallopian tubes.

669. Since 2010, Plaintiff Edge has endured an extensive course of medical treatment for an evolving combination of the symptoms described above.

670. This history and course of medical treatment is well-documented, and has included treatment for questionable iron deficiency and anemia beginning in December 2010; shortness of

breath, right arm pain, and back pain in April 2011; neuropathic pain and tremors beginning in May 2011; memory trouble beginning in October 2012; pain disorder, joint pain, hand swelling and headaches beginning in December 2012; an allergic reaction to eating eggs in January 2013 (which was new); worsening hand rashes in February 2013; fatigue beginning in March 2013; worsening menorrhagia beginning in July 2013; Mirena IUD placement in order to control heavy bleeding in May 2014; hematochezia beginning in January 2015; and right upper quadrant pain in March 2015.

671. In response to Plaintiff Edge's right upper quadrant pain, an ultrasound was performed on or about March 10, 2015, which noted "incidental ovoid hyperechoic liver lesion (19 mm, no halo, posterior segment) probably represent[ing] a benign cavernous hemangioma."

672. On or about July 18, 2017, Plaintiff Edge presented to Fairview Center for Women in Edina, Minnesota for a removal consult. She reported complaints of pelvic pain which is generally more severe on the left than her right and causes her to become nauseated. She further reported hair loss, joint pain, severe fatigue, headaches and tremors. An ultrasound indicated "Essures noted bilaterally, left device is deformed." She was assessed with "female pelvic pain, secondary to Essure devices," and surgical removal was recommended.

673. Due to continued pelvic pain, on or about November 29, 2017, Plaintiff Edge underwent a laparoscopic bilateral salpingectomy to remove the Essure® device performed by Dr. Presthus at Fairview Southdale Hospital. The Operative Report noted that "[t]he left tube did have a bend in it suggesting the Essure device was poking into the tube."

674. Since the removal surgery, Plaintiff Edge's symptomatology has largely resolved; however, she still experiences abdominal pain, joint pain, fatigue, migraines and painful periods.

675. Sometime in or around November 2016, Plaintiff Edge saw a legal advertisement describing a potential action to be filed against the manufacturers of the Essure® device. It was not

until seeing this advertisement that Plaintiff could reasonably have concluded that there is a causal relationship between her post-Essure[®] implantation symptomatology, a defect in the Essure[®] device, or any wrongdoing on the part of the manufacturer of the Essure[®] device.

T. AMY M. OLSON

676. Plaintiff Olson is forty (40) years old and resides in Detroit Lakes, Becker County, Minnesota.

1. Initial Essure[®] Procedure:

677. On or around April 20, 2012, Plaintiff Olson underwent the Essure[®] procedure, under local anesthesia with sedation, at Essentia Health St. Mary's – Detroit Lakes Clinic ("DLC"), Detroit Lakes, Becker County, Minnesota.

678. James Christensen, MD, implanted the Essure[®] device in Plaintiff Olson.

2. Post Essure[®] Procedure Condition and Treatment:

679. Plaintiff Olson underwent a HSG on or about July 16, 2012, which showed bilateral tubal occlusion.

680. Plaintiff Olson's post-procedure course has been marked by abdominal pain, diarrhea, nausea, pelvic pain, excessive menstruation, bloating feeling, night sweats and hot flashes, rashes, hair loss, decreased libido, and right sided pain before and after menses. Before Essure[®], Plaintiff had not experienced this combination of symptoms while not on birth control. Her menstrual periods were normal, and she had no problem with going about her daily life.

681. On or around October 13, 2015, Plaintiff Olson presented to DLC with complaints of feeling hot all the time, it being worse at night, and decreased libido. She was assessed with possible hot flashes and lab tests were ordered.

682. On or around July 1, 2016, Plaintiff Olson presented to DLC with complaints of abdominal bloating, low back discomfort, skin changes and allergic type reactions, and some

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vaginal discomfort with intercourse. Prior allergy testing was unremarkable.

683. Plaintiff Olson presented to Minnesota Gynecology and Surgery-Fairview OB/GYN for a consult on or about September 22, 2016. She reported complaints of feeling bloated constantly, night sweats and hot flashes, hair loss, skin rash, foggy memory, right-sided abdominal pain, dyspareunia, irregular/heavy menses and severe dysmenorrhea. She was assessed with “infection and inflammatory reaction due to prosthetic device, implant and graft in genital tract, pelvic pain, and excessive or frequent menstruation.” A pelvic ultrasound noted “[n]o uterine fibroids [and] [t]he Essure devices appear appropriately positioned.” The plan was to proceed with a laparoscopic supracervical hysterectomy with bilateral salpingectomy and removal of the Essure® devices.

684. On or around October 24, 2016, Plaintiff Olson underwent a laparoscopic supracervical hysterectomy, bilateral salpingectomy and cystoscopy performed by Dr. James Prethus at Fairview Southdale Hospital due to pelvic pain as a result of the Essure® device. The operative report noted the Essure® devices were removed bilaterally.

685. After the removal of the Essure® device, Plaintiff Olson’s symptoms largely resolved; however, she still experience skin sensitivity and hot flashes. Despite suffering from these symptoms for over three years, Plaintiff Olson’s symptoms resolved only after removal of her Essure® device. Until the removal, neither she nor her doctors could clearly correlate her problem as being associated with the device. After the removal, the cause of her problems became obvious, due to their resolution.

U. RACHAEL JOHNSON

686. Plaintiff Johnson is thirty-three (33) years old and resides in St. Louis, St. Louis County, Missouri.

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1. Initial Essure® Procedure:

687. On or around May 17, 2011, Plaintiff Johnson underwent the Essure® procedure under general anesthesia at Barnes Jewish Hospital in St. Louis, Missouri. Dr. Sangeeta Kaur performed the implant of the Essure® on Plaintiff Johnson.

688. Further, Plaintiff Johnson was not informed that the Essure® procedure as marketed was not intended to take place under general anesthesia and that the balance of risks and benefits of Essure® versus tubal ligation was unfavorable to Essure® under such circumstances.

2. Post Essure® Procedure Condition and Treatment:

689. Plaintiff's post-procedure course has been marked by menorrhagia, irregular menses, extreme fatigue, and weight gain. Before Essure®, Plaintiff's menstrual periods were not nearly as heavy, nor did they last as long, and she had no problem with going about her daily life.

690. Plaintiff Johnson presented for a follow up examination on June 3, 2011. Plaintiff Johnson reported no major problems during this encounter. Her weight at this time was documented to be 172 pounds.

691. Plaintiff Johnson had a HSG exam on September 26, 2011. The findings were unremarkable, and occlusion was viewed in both fallopian tubes.

692. Plaintiff Johnson's symptomatology developed gradually in the years following the Essure® implant procedure.

693. On October 19, 2016, Plaintiff Johnson presented for an annual well woman exam at the Betty Jean Kerr People's Health Center in St. Louis, Missouri. On this encounter, Plaintiff Johnson reported an eighteen-month recent history of irregular menses. Plaintiff declined hormonal treatment options.

694. Also, on October 16, 2016, Plaintiff Johnson's weight was documented to be 204 pounds, a gain of thirty-two pounds since Plaintiff Johnson's June 3, 2011 examination.

695. Despite Plaintiffs' developing symptoms, at no time has a physician or medical professional indicated to Plaintiff that there is a causal relationship between her post-Essure[®] implantation symptomatology and the Essure[®] device, a defect in the Essure[®] device.

696. Today, the Essure[®] devices remain implanted in Plaintiff, and she continues to experience a combination of the above symptoms. Plaintiff Johnson has an appointment with Dr. Genie Pierson at People's Health Center to discuss removal of the Essure[®] device. Plaintiff Johnson's menstrual cycle continues to be irregular and unpredictable, with menses occurring at unexpected times and occasionally twice in the same month.

697. Sometime in or around 2016, Plaintiff Johnson learned of a potential action to be filed against the manufacturers of the Essure[®] device. It was not until this time that Plaintiff could reasonably have concluded that there is a causal relationship between her post-Essure[®] implantation symptomatology, a defect in the Essure[®] device, or any wrongdoing on the part of the manufacturer of the Essure[®] device.

V. BETTY KILLY

698. Plaintiff Killy is thirty-five (35) years old and resides in Las Vegas, Clark County, Nevada.

1. Initial Essure[®] Procedure:

699. On or around July 3, 2014, Plaintiff Killy underwent the Essure[®] procedure at UP-Smiley Lane Clinics in Columbia, Missouri.

700. Courtney Leigh Barnes, MD, implanted the Essure[®] device in Plaintiff Killy.

701. Plaintiff Killy was directed toward Essure[®] by Dr. Barnes because it was a simple, in-office procedure that did not require anesthesia. She was assured that Essure[®] was as safe as or safer than tubal ligation.

2. Post Essure® Procedure Condition and Treatment:

702. On or around October 8, 2014, Plaintiff Killy underwent a HSG at Womens and Childrens Hospital in Columbia, Missouri, which confirmed the position of the Essure® implants and determined that occlusion of the bilateral fallopian tubes had occurred.

703. Plaintiff Killy's post-procedure course has been marked by pelvic pain and dysfunctional uterine bleeding.

704. For the year after her HSG, Plaintiff Killy was unable to seek treatment for her symptoms because she lost her health insurance when she moved from Missouri to Nevada.

705. On or around December 14, 2015, Plaintiff Killy complained to Dr. Liu in Las Vegas, Nevada of the heavy uterine bleeding and severe pelvic pain that she had been enduring since the implant of the Essure® device. Dr. Liu recommended a hysteroscopy D & C with an endometrial ablation.

706. On or around February 26, 2016, Plaintiff Killy underwent a diagnostic laparoscopy and bilateral salpingectomy, hysteroscopy D & C and a NovaSure endometrial ablation at the Las Vegas Surgery Center due to her heavy uterine bleeding and pelvic pain during which both Essure® coils were successfully removed. According to her medical records, there was evidence of bleeding in the endometrial cavity noted during her surgery.

707. After the removal of the Essure® device all of Plaintiff Killy's symptoms resolved. Her menstrual periods are normal, and her heavy vaginal bleeding has ceased. Until the removal, neither she nor her doctors could clearly correlate her problems as being associated with the device. After the removal, the cause of her problems became obvious, due to their resolution.

W. Amber Riggs (Stewart)

708. Plaintiff Riggs is thirty-seven (37) years old and resides in Portsmouth, Scioto County, Ohio.

1. Initial Essure® Procedure:

709. On or around August 9, 2012, Plaintiff Riggs underwent the Essure® procedure (ESS305, Lot #959220) and Thermachoice Endometrial Ablation under general anesthesia at Pike Community Hospital in Waverly, Ohio.

710. George Pettit, MD, implanted the Essure® device in Plaintiff Riggs.

711. Plaintiff Riggs was directed towards Essure® by Dr. Pettit, and was advised that it was permanent, safe and effective.

712. Further, Plaintiff Riggs was not informed that the Essure® procedure as marketed was not intended to take place under general anesthesia and that the balance of risks and benefits of Essure® versus tubal ligation was unfavorable to Essure® under such circumstances.

2. Post Essure® Procedure Condition and Treatment:

713. Plaintiff Riggs underwent a HSG exam on or about November 15, 2012, which noted bilateral tubal occlusion.

714. Plaintiff Riggs' post-procedure course has been marked by abdominal/pelvic pain, joint pain, dyspareunia, brittle teeth, fatigue, hair loss, rashes, urinary tract infections and autoimmune type symptoms.

715. Plaintiff Riggs presented to Holzer Athens on or about June 13, 2013, with complaints of a rash on her back. She was assessed with a mild form of systemic lupus erythematosus and Sicca syndrome and noted to have a photosensitive rash on her arms, synovitis and a positive ANA.

716. On or around July 9, 2013, Plaintiff Riggs presented for her annual exam with Dr. George Pettit. She reported complaints of lower left quadrant pain and leaking urine. She was assessed with abdominal pain.

717. Plaintiff Riggs returned to Holzer Athens for a follow up visit on or about July 8, 2014. She reported worsening pain in her fingers, right knee, bilateral elbows and heels, sun sensitivity and rashes, hair loss, dry eyes and mouth, sores in her nose and mouth and swollen hands and feet. Her assessments included fibromyalgia, systemic lupus erythematosus and a urinary tract infection. She was referred to cardiology for a consult.

718. On or about August 14, 2014, Plaintiff Riggs presented to Holzer Athens for a cardiology consult with Dr. C. Lynn Linkous. She reported having occasional chest pain and palpitations. An echocardiogram showed that her pericardial effusion had resolved.

719. For the next several years, Plaintiff Riggs continued to seek treatment for symptoms related to fibromyalgia and systemic lupus erythematosus. She reported continued complaints of back pain, fatigue, joint pain and swelling and rashes.

720. On or about May 29, 2018, Plaintiff Riggs was tested for a nickel allergy and was noted to have a positive reaction to nickel.

721. On or about June 14, 2018, Plaintiff Riggs presented to Whitehall Family Health Center and reported complaints of pelvic pain, hair loss, unexplained abdominal pain and symptoms related to a nickel allergy. She was assessed with pelvic pain and a nickel allergy, and referred to gynecology.

722. Plaintiff Riggs still has the Essure[®] device surgically implanted; however, she is currently seeking a physician who will remove the device in order to address her symptomatology.

723. Despite suffering from these symptoms for almost six (6) years, Plaintiff Riggs did not realize, until she saw a legal advertisement sometime in or around February 2017, that her symptoms were also being experienced and suffered by thousands of other women who had been implanted with the Essure[®] device. It was at this time that she truly understood that her symptoms were related to Essure[®] and the legal options available to her.

X. CONNIE HARRIS

724. Plaintiff Harris is thirty-eight (38) years old and resides in Easley, Pickens County, South Carolina.

1. Initial Essure® Procedure:

725. On or around June 27, 2012, Plaintiff Harris underwent the Essure® procedure at Greenville Memorial Hospital in Greenville, Greenville County, South Carolina.

726. Shawna Ruple, MD, implanted the Essure® device in Plaintiff Harris.

2. Post Essure® Procedure Condition and Treatment:

727. On or around October 1, 2012, Plaintiff Harris underwent a HSG exam which noted occlusion of the left fallopian tube but the right tube was patent and the Essure® coil had migrated into Plaintiff's left hemipelvis.

728. Due to the migration of the right Essure® coil, on or around October 24, 2012, a second attempt was made to place the right Essure® coil but was unsuccessful. However, the migrated right Essure® coil was not removed at that time.

729. On or around February 18, 2013, Plaintiff Harris presented to the Greenville Medical Center Clinic for a consultation for permanent sterilization due to the migration of the Essure® device. She was scheduled for a laparoscopic tubal ligation.

730. On or around May 15, 2013, Plaintiff Harris underwent a laparoscopic tubal ligation and removal of the migrated Essure® coil performed by Dr. Benjie Mills at Greenville Memorial Hospital. Two filshie clips were placed on the left fallopian tube and the right tube was cauterized since there was no Essure® coil found in the tube. The operative report noted the right Essure® device was located in the omentum which was removed.

731. Plaintiff Harris continued to suffer symptoms related to the Essure® implantation following her surgery, including heavy bleeding, constant spotting between menses,

abdominal/pelvic pain, severe cramping and brittle teeth. While she does not have a diagnosed nickel allergy at this time, she is unable to wear “fake” or “costume” jewelry, which often contains nickel because it causes a rash and skin discoloration.

732. Based upon information and belief, Plaintiff Harris still has the Essure[®] device surgically implanted in her left fallopian tube.

733. Plaintiff Harris did not realize that she had a legal remedy due to her injuries from Essure[®] until she saw a legal advertisement describing symptoms like hers which were also being experienced and suffered by thousands of other women who had been implanted with the Essure[®] device. It was at this time that she truly understood that her symptoms were related to Essure[®] and the legal options available to her.

Y. MICHELLE L. THOMAS

734. Plaintiff Thomas is thirty-two (32) years old and is a citizen and resident of St. Louis, St. Louis County, Missouri.

1. Initial Essure[®] Procedure:

735. On or around July 20, 2011, Plaintiff Thomas underwent the Essure[®] procedure at Barnes-Jewish Hospital in St. Louis, St. Louis County, Missouri

736. Denise Willers, MD implanted the Essure[®] device in Plaintiff Thomas who was only twenty-five (25) years old at the time of her sterilization procedure.

737. Plaintiff Thomas was never informed that Essure[®] was not an appropriate form of birth control for such a young woman, as her opinion about sterilization may change, leaving her with regret; and because it is typical for young women to experience problems with their menstrual cycles, which are treated with hormonal birth control but cannot be treated with Essure[®].

2. Post Essure® Procedure Condition and Treatment:

738. Plaintiff Thomas' post-procedure course has been marked by increasingly severe pain and discomfort, including but not limited to heavy and irregular menstrual cycle, chronic abdominal and pelvic pain, pain during intercourse, excessive weight gain, and tooth decay.

739. Plaintiff Thomas subsequently sought treatment for her symptoms at BJC-Christian Hospital and from her physicians in St. Louis, Missouri, but her treating physicians were unable to resolve her symptoms.

740. Plaintiff Thomas has suffered from these symptoms for over seven (7) years, and yet her treating physicians keep telling her that her pain is not being caused by the Essure® device. Plaintiff did not realize, until she saw a legal advertisement, that her symptoms were also being experienced and suffered by thousands of other women who had been implanted with the Essure® device. It was at this time, she truly understood that her symptoms were related to Essure®.

Z. MICHELLE D. SEIBER

741. Plaintiff Seiber is forty-seven (47) years old and is a citizen and resident of St. Louis, St. Louis County, Missouri.

1. Initial Essure® Procedure:

742. On or around March 17, 2014, Plaintiff Seiber underwent the Essure® procedure at Missouri Baptist Medical Center in St. Louis, St. Louis County, Missouri

743. Stacey Coombes, MD, implanted the Essure® device in Plaintiff Seiber.

2. Post Essure® Procedure Condition and Treatment:

744. Plaintiff Seiber's post-procedure course has been marked by increasingly severe pain and discomfort, including abdominal and pelvic pain, and abnormal uterine bleeding.

745. Plaintiff Seiber subsequently sought treatment for her symptoms at Missouri Baptist Medical Center and SSM Health DePaul Hospital in St. Louis, Missouri, and from other physicians in St. Louis, Missouri, but her treating physicians were unable to resolve her symptoms.

746. On or around May 2, 2018, Plaintiff Seiber underwent surgery to remove her fallopian tubes, Essure® coils, and uterus at Missouri Baptist Medical Center in St. Louis, Missouri.

747. Plaintiff Seiber's symptoms resolved following her explant surgery, but she is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious permanent injuries.

748. Despite suffering from these symptoms for four (4) years, Plaintiff Seiber's symptoms resolved only after removal of her Essure® device. Until the removal, neither she nor her treating physicians could clearly correlate her problems as being associated with the device. After the removal, the cause of her problems became obvious due to their resolution.

AA. JENNIFER C. CARLSON

749. Plaintiff Carlson is thirty-seven (37) years old and is a citizen and resident of Chesapeake, Virginia.

1. Initial Essure® Procedure:

750. On or around January 4, 2013, Plaintiff Carlson underwent the Essure® procedure at Planned Parenthood of Southeastern Virginia in Virginia Beach, Virginia.

751. Richard Willard, MD, implanted the Essure® device in Plaintiff Carlson.

2. Post Essure® Procedure Condition and Treatment:

752. Plaintiff Carlson's post-procedure course has been marked by increasingly severe pain and discomfort, including heavy and irregular menstrual cycle and chronic abdominal and pelvic pain.

753. Plaintiff Carlson subsequently sought treatment for her symptoms at Family Medicine Clinic PCMH in Portsmouth, Virginia, but her treating physicians were unable to resolve her symptoms.

754. On or around November 7, 2014, Plaintiff Carlson underwent surgery to remove her fallopian tubes, Essure[®] coils, and uterus at the North Carolina Center for Reproductive Medicine in Cary, North Carolina.

755. Plaintiff Carlson's symptoms resolved following her explant surgery, but she is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious permanent injuries.

756. Plaintiff Carlson suffered from these symptoms for nearly two (2) years, while her treating physicians kept telling her that her pain was not being caused by the Essure[®] device. Plaintiff did not realize, until she saw an advertisement online, that her symptoms were also being experienced and suffered by thousands of other women who had been implanted with the Essure[®] device. It was at this time, she truly understood that her symptoms were related to Essure[®].

BB. LAKESHIA N. EDWARDS

757. Plaintiff Edwards is thirty-two (32) years old and is a citizen and resident of Little Rock, Pulaski County, Arkansas.

1. Initial Essure[®] Procedure:

758. On or around July 30, 2013, Plaintiff Edwards underwent the Essure[®] procedure at Parkhill Clinic for Women in Fayetteville, Washington County, Arkansas.

759. Scott Bailey, MD, implanted the Essure[®] device in Plaintiff Edwards who was only twenty-seven (27) years old at the time of her sterilization procedure.

760. Plaintiff Edwards was never informed that Essure[®] was not an appropriate form of birth control for such a young woman, as her opinion about sterilization may change, leaving her

with regret; and because it is typical for young women to experience problems with their menstrual cycles, which are treated with hormonal birth control but cannot be treated with Essure®.

2. Post Essure® Procedure Condition and Treatment:

761. Plaintiff Edwards' post-procedure course has been marked by increasingly severe pain and discomfort, including heavy and irregular menstrual cycle and chronic abdominal and pelvic pain.

762. Plaintiff Edwards subsequently sought treatment for her symptoms at Women's Pavilion in Little Rock, Arkansas and various hospitals and doctors in Little Rock, Arkansas and the surrounding areas, but her treating physicians were unable to resolve her symptoms.

763. Plaintiff Edwards has suffered from these symptoms for five (5) years, and yet her treating physicians keep telling her that her pain is not being caused by the Essure® device. Plaintiff did not realize, until she saw a legal advertisement in July of 2016, that her symptoms were also being experienced and suffered by thousands of other women who had been implanted with the Essure® device. It was at this time, she truly understood that her symptoms were related to Essure®.

CC. TIESHA M. MOSLEY

764. Plaintiff Mosley is thirty-nine (39) years old and is a citizen and resident of Stafford, Fort Bend County, Texas.

1. Initial Essure® Procedure:

765. On or around January 31, 2013, Plaintiff Mosley underwent the Essure® procedure at Memorial Hermann Sugar Land Hospital in Fort Bend County, Sugar Land, Texas.

766. Lauren Phillips, MD, implanted the Essure® device in Plaintiff Mosley.

2. Post Essure® Procedure Condition and Treatment:

767. Plaintiff Mosley's post-procedure course has been marked by increasingly severe pain and discomfort, including chronic abdominal and pelvic pain, frequent infections and vaginal

discharge.

768. Plaintiff Mosley subsequently sought treatment for her symptoms at Bee Busy Wellness Center in Houston, Texas, and from various other hospitals in the surrounding area, but her treating physicians were unable to resolve her symptoms.

769. Plaintiff Mosley has suffered from these symptoms for over five (5) years, and yet her treating physicians keep telling her that her pain is not being caused by the Essure[®] device. Plaintiff did not realize, until she saw a legal advertisement, that her symptoms were also being experienced and suffered by thousands of other women who had been implanted with the Essure[®] device. It was at this time, she truly understood that her symptoms were related to Essure[®].

DD. KRISTY R. SILVERS

770. Plaintiff Silvers is thirty-three (33) years old and is a citizen and resident of Dalton, Whitfield County, Georgia.

1. Initial Essure[®] Procedure:

771. On or around February 14, 2008, Plaintiff Silvers underwent the Essure[®] procedure at North Georgia Women's Center in Whitfield County, Dalton, Georgia.

772. J. Douglas Harbin, MD, implanted the Essure[®] device in Plaintiff Silvers who was only twenty-two (22) years old at the time of her sterilization procedure

773. Plaintiff Silvers was never informed that Essure[®] was not an appropriate form of birth control for such a young woman, as her opinion about sterilization may change, leaving her with regret; and because it is typical for young women to experience problems with their menstrual cycles, which are treated with hormonal birth control but cannot be treated with Essure[®].

2. Post Essure[®] Procedure Condition and Treatment:

774. Plaintiff Silvers' post-procedure course has been marked by increasingly severe pain and discomfort, including heavy and irregular menstrual cycle, irregular vaginal bleeding,

and chronic abdominal and pelvic pain.

775. Plaintiff Silvers subsequently sought treatment for her symptoms at Hamilton Medical Center, and from her other physicians in Dalton, Georgia, but her treating physicians were unable to resolve her symptoms.

776. Plaintiff Silvers has suffered from these symptoms for more than ten (10) years, and yet her treating physicians keep telling her that her pain is not being caused by the Essure[®] device. Plaintiff did not realize, until she saw an advertisement online, that her symptoms were also being experienced and suffered by thousands of other women who had been implanted with the Essure[®] device. It was at this time, she truly understood that her symptoms were related to Essure[®].

EE. MICHELLE L. BRANHAM

777. Plaintiff Branham is forty-four (44) years old and is a citizen and resident of Midlothian, Cook County, Illinois.

1. Initial Essure[®] Procedure:

778. On or about October 31, 2015, Plaintiff Branham underwent the Essure[®] procedure at Planned Parenthood of Illinois in Kane County, Aurora, Illinois.

779. Virgil Reid, MD, implanted the Essure[®] device in Plaintiff Branham.

2. Post Essure[®] Procedure Condition and Treatment:

780. Plaintiff Branham's post-procedure course has been marked by increasingly severe pain and discomfort, including chronic abdominal and pelvic pain and irregular menstrual cycle.

781. Plaintiff Branham subsequently sought treatment for her symptoms at her primary care physician's office in Orland Park, Illinois and from various other immediate care facilities in and around Orland Park, Illinois, but her treating physicians were unable to resolve her symptoms.

782. Plaintiff Branham has suffered from these symptoms for nearly three (3) years, and yet her treating physicians keep telling her that her pain is not being caused by the Essure® device. Plaintiff did not realize, until she saw an advertisement online, that her symptoms were also being experienced and suffered by thousands of other women who had been implanted with the Essure® device. It was at this time, she truly understood that her symptoms were related to Essure®.

FF. ELIZABETH A. CLAAR

783. Plaintiff Claar is forty-nine (49) years old and is a citizen and resident of West Farmington, Trumbull County, Ohio.

1. Initial Essure® Procedure:

784. On or about December 15, 2011, Plaintiff Claar underwent the Essure® procedure at Cortland Ob/Gyn Associates in Trumbull County, Warren, Ohio.

785. Amine Abdul-Aal, MD, implanted the Essure® device in Plaintiff Claar.

2. Post Essure® Procedure Condition and Treatment:

786. Plaintiff Claar's post-procedure course has been marked by increasingly severe pain and discomfort, including chronic pelvic and abdominal pain, irregular uterine bleeding and weight gain.

787. Plaintiff Claar subsequently sought treatment for her symptoms at Edward G. Meyers, DO, Family Practice in Warren, Ohio, and from other physicians in Warren, Ohio, but her treating physicians were unable to resolve her symptoms.

788. On or around February 21, 2014, Plaintiff Claar underwent surgery to remove her fallopian tubes, Essure® coils, and uterus at Mercy Health – St. Joseph Warren Hospital in Warren, Ohio.

789. Plaintiff Claar's symptoms resolved following her explant surgery, but she is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and

she has otherwise suffered serious permanent injuries.

790. Despite suffering from these symptoms for almost three (3) years, Plaintiff Claar's symptoms resolved only after removal of her Essure[®] device.

791. Plaintiff Claar suffered from these symptoms for nearly three (3) years, while her treating physicians kept telling her that her pain was not being caused by the Essure[®] device. Plaintiff did not realize, until she saw an advertisement online, that her symptoms were also being experienced and suffered by thousands of other women who had been implanted with the Essure[®] device. It was at this time, she truly understood that her symptoms were related to Essure[®].

GG. TASCHA FARNSWORTH

792. Plaintiff Farnsworth is thirty-two (32) years old and is a citizen and resident of Rancho Murieta, Sacramento County, California.

1. Initial Essure[®] Procedure:

793. On or about February 4, 2013, Plaintiff Farnsworth underwent the Essure[®] procedure at Point West Medical Offices in Sacramento, Sacramento County, California.

794. Karyl Andolina, MD, implanted the Essure[®] device in Plaintiff Farnsworth who was only twenty-seven (27) years old at the time of her sterilization procedure.

795. Plaintiff Farnsworth was never informed that Essure[®] was not an appropriate form of birth control for such a young woman, as her opinion about sterilization may change, leaving her with regret; and because it is typical for young women to experience problems with their menstrual cycles, which are treated with hormonal birth control but cannot be treated with Essure[®].

2. Post Essure[®] Procedure Condition and Treatment:

796. Plaintiff Farnsworth's post-procedure course has been marked by increasingly severe pain and discomfort, including chronic pelvic pain and abnormal bleeding.

797. Plaintiff Farnsworth underwent a HSG exam on or about June 10, 2013, which showed bilateral tubal occlusion.

798. Plaintiff Farnsworth subsequently sought treatment for her symptoms with various physicians within the Kaiser Permanente Medical Group in Sacramento, California, but her treating physicians were unable to resolve her symptoms.

799. On or around June 16, 2015, Plaintiff Farnsworth underwent surgery to remove her fallopian tubes, Essure[®] coils, and uterus at Kaiser Permanente South Sacramento Medical Center in Sacramento, California.

800. Plaintiff Farnsworth's symptoms resolved following her explant surgery, but she is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious permanent injuries.

801. Despite suffering from these symptoms for over two (2) years, Plaintiff Farnsworth's symptoms resolved only after removal of her Essure[®] device.

802. Plaintiff Farnsworth suffered from these symptoms for over two (2) years, while her treating physicians kept telling her that her pain was not being caused by the Essure[®] device. Plaintiff did not realize, until she saw an advertisement online, that her symptoms were also being experienced and suffered by thousands of other women who had been implanted with the Essure[®] device. It was at this time, she truly understood that her symptoms were related to Essure[®].

HH. TAMIKA K. JACKSON

803. Plaintiff Jackson is thirty-seven (37) years old and is a citizen and resident of Baltimore, Baltimore County, Maryland.

1. Initial Essure[®] Procedure:

804. On or about October 18, 2012, Plaintiff Jackson underwent the Essure[®] procedure at the University of Maryland Medical Center Women's Health in Baltimore, Baltimore County,

Maryland.

805. Katrina Mark, MD, implanted the Essure[®] device in Plaintiff Jackson.

2. Post Essure[®] Procedure Condition and Treatment:

806. Plaintiff Jackson's post-procedure course has been marked by increasingly severe pain and discomfort, including chronic abdominal, pelvic and back pain.

807. Plaintiff Jackson subsequently sought treatment for her symptoms at Northwest Hospital Center in Randallstown, Maryland, and from her various physicians in and around Baltimore, Maryland, but her treating physicians were unable to resolve her symptoms.

808. Plaintiff Jackson has suffered from these symptoms for nearly six (6) years, and yet her treating physicians keep telling her that her pain is not being caused by the Essure[®] device. Plaintiff did not realize, until she saw a legal advertisement, that her symptoms were also being experienced and suffered by thousands of other women who had been implanted with the Essure[®] device. It was at this time, she truly understood that her symptoms were related to Essure[®].

II. JAMIE D. KAMBARIAN

809. Plaintiff Kambarian is forty-eight (48) years old and is a citizen and resident of Godfrey, Madison County, Illinois.

1. Initial Essure[®] Procedure:

810. On or about March 23, 2007, Plaintiff Kambarian underwent the Essure[®] procedure at West County Ob/Gyn in St. Louis, St. Louis County, Missouri.

811. Thomas Whalen, MD, implanted the Essure[®] device in Plaintiff Kambarian.

2. Post Essure[®] Procedure Condition and Treatment:

812. Plaintiff Kambarian's post-procedure course has been marked by increasingly severe pain and discomfort, including heavy and irregular menstrual cycle, abnormal uterine bleeding and chronic pelvic pain.

813. Plaintiff Kambarian subsequently sought treatment for her symptoms at Alton Memorial Hospital in Alton, Illinois and Barnes-Jewish Hospital – Washington University in St. Louis, Missouri, but her treating physicians were unable to resolve her symptoms.

814. On or around October 14, 2013, Plaintiff Kambarian underwent surgery to remove her fallopian tubes, Essure® coils, and uterus at Barnes Jewish Hospital in St. Louis, Missouri.

815. Plaintiff Kambarian's symptoms resolved following her explant surgery, but she is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious permanent injuries.

816. Despite suffering from these symptoms for over six (6) years, Plaintiff Kambarian's symptoms resolved only after removal of her Essure® device.

817. Plaintiff Kambarian suffered from these symptoms for over six (6) years, while her treating physicians kept telling her that her pain was not being caused by the Essure® device. Plaintiff did not realize, until she saw an advertisement online, that her symptoms were also being experienced and suffered by thousands of other women who had been implanted with the Essure® device. It was at this time, she truly understood that her symptoms were related to Essure®.

JJ. SHAMICA L. JONES

818. Plaintiff Jones is thirty-nine (39) years old and is a citizen and resident of Elk Grove, Sacramento County, California.

1. Initial Essure® Procedure:

819. On or about May 29, 2014, Plaintiff Jones underwent the Essure® procedure at Kaiser Permanente Elk Grove Medical Offices in Elk Grove, Sacramento County, California.

820. Dhaliwal Kamalbir, MD, implanted the Essure® device in Plaintiff Jones.

2. Post Essure® Procedure Condition and Treatment:

821. Plaintiff Jones' post-procedure course has been marked by increasingly severe pain and discomfort, including chronic pelvic pain and abnormal bleeding.

822. Plaintiff Jones underwent a HSG exam on or about August 29, 2014, which showed bilateral tubal occlusion.

823. Plaintiff Jones subsequently sought treatment for her symptoms with various physicians within the Kaiser Permanente Medical Group in and around Sacramento, California, but her treating physicians were unable to resolve her symptoms.

824. On or around December 21, 2016, Plaintiff Jones underwent surgery to remove her fallopian tubes, Essure® coils, and uterus at Kaiser Permanente South Sacramento Medical Center in Sacramento, California.

825. Plaintiff Jones' symptoms resolved following her explant surgery, but she is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious permanent injuries.

826. Despite suffering from these symptoms for more than two (2) years, Plaintiff Jones' symptoms resolved only after removal of her Essure® device. Until the removal, neither she nor her treating physicians could clearly correlate her problems as being associated with the device. After the removal, the cause of her problems became obvious due to their resolution.

KK. SHEENA MACKEY

827. Plaintiff Mackey is thirty-one (31) years old and is a citizen and resident of Canyon Lake, Comal County, Texas.

1. Initial Essure® Procedure:

828. On or about September 28, 2010, Plaintiff Mackey underwent the Essure® procedure at New Braunfels Ob/Gyn in New Braunfels, Comal County, Texas.

829. Nagakrishna Reddy, MD, implanted the Essure[®] device in Plaintiff Mackey who was only twenty-three (23) years old at the time of her sterilization procedure.

830. Plaintiff Mackey was never informed that Essure[®] was not an appropriate form of birth control for such a young woman, as her opinion about sterilization may change, leaving her with regret; and because it is typical for young women to experience problems with their menstrual cycles, which are treated with hormonal birth control but cannot be treated with Essure[®].

2. Post Essure[®] Procedure Condition and Treatment:

831. Plaintiff Mackey's post-procedure course has been marked by increasingly severe pain and discomfort, including but not limited to chronic pelvic and abdominal pain and abnormal vaginal bleeding.

832. Plaintiff Mackey underwent a HSG exam on or about October 2, 2017, which showed bilateral tubal occlusion.

833. Plaintiff Mackey subsequently sought treatment for her symptoms at New Braunfels Ob/Gyn in New Braunfels, Texas, and University Hospital in San Antonio, Texas, but her treating physicians were unable to resolve her symptoms.

834. Plaintiff Mackey has suffered from these symptoms for nearly (8) years, and yet her treating physicians keep telling her that her pain is not being caused by the Essure[®] device. Plaintiff did not realize, until she saw a legal advertisement, that her symptoms were also being experienced and suffered by thousands of other women who had been implanted with the Essure[®] device. It was at this time, she truly understood that her symptoms were related to Essure[®].

LL. MARIA D. LOPEZ

835. Plaintiff Lopez is twenty-eight (28) years old and is a citizen and resident of Odessa, Ector County, Texas.

1. Initial Essure® Procedure:

836. On or about April 19, 2012, Plaintiff Lopez underwent the Essure® procedure at Permian Women's Center in Ector County, Odessa, Texas.

837. Pill Raja, MD, implanted the Essure® device in Plaintiff Lopez who was only twenty-two (22) years old at the time of her sterilization procedure.

838. Plaintiff Lopez was never informed that Essure® was not an appropriate form of birth control for such a young woman, as her opinion about sterilization may change, leaving her with regret; and because it is typical for young women to experience problems with their menstrual cycles, which are treated with hormonal birth control but cannot be treated with Essure®.

2. Post Essure® Procedure Condition and Treatment:

839. Plaintiff Lopez's post-procedure course has been marked by increasingly severe pain and discomfort, including chronic abdominal and pelvic pain, irregular menstruation and abnormal uterine and vaginal bleeding.

840. Plaintiff Lopez subsequently sought treatment for her symptoms at Permian Women's Center and The University of Texas Medical Branch – CMC, and from her other physicians in Odessa, Texas, but her treating physicians were unable to resolve her symptoms.

841. Plaintiff Lopez has suffered from these symptoms for over six (6) years, and yet her treating physicians keep telling her that her pain is not being caused by the Essure® device. Plaintiff did not realize, until she saw a legal advertisement, that her symptoms were also being experienced and suffered by thousands of other women who had been implanted with the Essure® device. It was at this time, she truly understood that her symptoms were related to Essure®.

MM. BRITTANY D. VEIT

842. Plaintiff Veit is twenty-nine (29) years old and is a citizen and resident of Cross Lanes, Kanawha County, West Virginia.

1. Initial Essure® Procedure:

843. On or about June 9, 2017, Plaintiff Veit underwent the Essure® procedure at Thomas Memorial Hospital in Kanawha County, South Charleston, West Virginia.

844. Bassam N. Shamma, MD, implanted the Essure® device in Plaintiff Veit who was only twenty-eight (28) years old at the time of her sterilization procedure.

845. Plaintiff Veit was never informed that Essure® was not an appropriate form of birth control for such a young woman, as her opinion about sterilization may change, leaving her with regret; and because it is typical for young women to experience problems with their menstrual cycles, which are treated with hormonal birth control but cannot be treated with Essure®.

2. Post Essure® Procedure Condition and Treatment:

846. Plaintiff Veit's post-procedure course has been marked by increasingly severe pain and discomfort, including chronic pelvic pain, irregular menstruation and vaginal discharge. Plaintiff Veit is allergic to nickel.

847. Plaintiff Veit underwent a HSG exam on or about September 8, 2017, which showed bilateral tubal occlusion.

848. Plaintiff Veit subsequently sought treatment for her symptoms at Saint Mary's Family Care in Huntington, West Virginia, and from her other physicians in and around Cross Lanes, West Virginia, but her treating physicians were unable to resolve her symptoms.

849. Plaintiff Veit has suffered from these symptoms for over a year, and yet her treating physicians keep telling her that her pain is not being caused by the Essure® device. Plaintiff did not realize, until she saw a legal advertisement, that her symptoms were also being experienced and suffered by thousands of other women who had been implanted with the Essure® device. It was at this time, she truly understood that her symptoms were related to Essure®.

NN. JODI L. WHITE

850. Plaintiff White is thirty-four (34) years old and is a citizen and resident of San Antonio, Bexar County, Texas.

1. Initial Essure® Procedure:

851. On or about March 24, 2009, Plaintiff White underwent the Essure® procedure at Geary Community Hospital in Geary County, Junction City, Kansas.

852. Anwar K. Khoury, MD, implanted the Essure® device in Plaintiff White who was only twenty-five (25) years old at the time of her sterilization procedure.

853. Plaintiff White was never informed that Essure® was not an appropriate form of birth control for such a young woman, as her opinion about sterilization may change, leaving her with regret; and because it is typical for young women to experience problems with their menstrual cycles, which are treated with hormonal birth control but cannot be treated with Essure®.

2. Post Essure® Procedure Condition and Treatment:

854. Plaintiff White's post-procedure course has been marked by increasingly severe pain and discomfort, including chronic abdominal and pelvic pain, irregular menstruation and frequent infections and discharge.

855. Plaintiff White subsequently sought treatment for her symptoms at Saline County Health Department in Salina, Kansas, and from her other physicians in San Antonio, Texas, but her treating physicians were unable to resolve her symptoms.

856. Plaintiff White has suffered from these symptoms for over eight (8) years, and yet her treating physicians keep telling her that her pain is not being caused by the Essure® device. Plaintiff did not realize, until she saw a legal advertisement, that her symptoms were also being experienced and suffered by thousands of other women who had been implanted with the Essure® device. It was at this time, she truly understood that her symptoms were related to Essure®.

OO. AMBER ESPINOZA

857. Plaintiff Espinoza is twenty-eight (28) years old and is a citizen and resident of Glendale, Arapahoe County, Colorado.

1. Initial Essure® Procedure:

858. On or about November 24, 2014, Plaintiff Espinoza underwent the Essure® procedure at Mile High Ob-Gyn in Denver, Arapahoe County, Colorado.

859. Jennifer Ann Linhorst, MD, implanted the Essure® device in Plaintiff Espinoza who was only twenty-four (24) years old at the time of her sterilization procedure.

860. Plaintiff Espinoza was never informed that Essure® was not an appropriate form of birth control for such a young woman, as her opinion about sterilization may change, leaving her with regret; and because it is typical for young women to experience problems with their menstrual cycles, which are treated with hormonal birth control but cannot be treated with Essure®.

2. Post Essure® Procedure Condition and Treatment:

861. Plaintiff Espinoza's post-procedure course has been marked by increasingly severe pain and discomfort, including chronic pelvic pain, uterine cramping and abnormal bleeding.

862. Plaintiff Espinoza underwent a HSG exam on or about February 20, 2015, which showed bilateral tubal occlusion.

863. Plaintiff Espinoza subsequently sought treatment for her symptoms at Mile High Ob-Gyn in Denver, Colorado and with the Metro Community Provider Network in Englewood, Colorado, but her treating physicians were unable to resolve her symptoms.

864. On or around September 19, 2017, Plaintiff Espinoza underwent surgery to remove her fallopian tubes, Essure® coils, and uterus at St. Anthony North Health Campus in Westminster, Colorado.

865. Plaintiff Espinoza's symptoms resolved following her explant surgery, but she is prevented from practicing and enjoying the activities of daily life she enjoyed pre-operatively, and she has otherwise suffered serious permanent injuries.

866. Despite suffering from these symptoms for nearly three (3) years, Plaintiff Espinoza's symptoms resolved only after removal of her Essure[®] device. Until the removal, neither she nor her treating physicians could clearly correlate her problems as being associated with the device. After the removal, the cause of her problems became obvious due to their resolution.

PP. SHERRI HELMS

867. Plaintiff Helms is forty-two (42) years old and resides in Warren, Trumbull County, Ohio.

1. Initial Essure[®] Procedure:

868. Upon information and belief, on or around March 11, 2011, Plaintiff Helms underwent the Essure[®] procedure at Trumbull Memorial Hospital in Warren, Ohio. Anthony DeSalvo, MD, implanted the Essure[®] device in Plaintiff Helms.

869. Further, Plaintiff Helms was not informed that the Essure[®] procedure as marketed was not intended to take place under general anesthesia and that the balance of risks and benefits of Essure[®] versus tubal ligation was unfavorable to Essure[®] under such circumstances.

870. Plaintiff Helms was directed toward Essure[®] by her providers.

2. Post Essure[®] Procedure Condition and Treatment:

871. Plaintiff Helms' post-procedure course has been marked by severe pain and discomfort, including, but not limited to, irregular and heavy menstrual periods, pelvic pain, weight gain and dental issues. Before Essure[®], she had not experienced this combination of symptoms, and she had no problem going about her daily life.

872. After undergoing the Essure[®] procedure, Plaintiff Helms spent five years seeking treatment for her symptoms from various medical providers in Ohio.

873. Upon information and belief, sometime in or about June 2016, Plaintiff Helms underwent a total hysterectomy and bilateral salpingectomy performed by Dr. Amine Abdul-Aal in Warren, Ohio.

874. Since the removal of the Essure[®] device, Plaintiff Helms' symptomology has completely resolved.

875. Plaintiff Helms did not realize that she had a legal remedy due to her injuries from Essure[®] until she saw a legal advertisement, sometime in or around September 2016, describing symptoms like hers which were also being experienced by thousands of other women who had been implanted with the Essure[®] device. It was at this time that she truly understood that her symptoms were related to Essure[®] and the legal options available to her.

QQ. SARAH WALKER

876. Plaintiff Walker is twenty-seven (27) years old and resides in Provo, Utah County, Utah.

1. Initial Essure[®] Procedure:

877. Upon information and belief, sometime in or around October 2015, Plaintiff Walker underwent the Essure[®] procedure at Revere Medical Center in Pleasant Grove, Utah.

878. Matthew Clark, MD, implanted the Essure[®] device in Plaintiff Walker who was only twenty-five (25) years old at the time of her sterilization procedure.

879. Plaintiff Walker was directed toward Essure[®] by her providers. It was her understanding that Essure[®] was as safe or safer than a bilateral tubal ligation.

2. Post Essure® Procedure Condition and Treatment:

880. Plaintiff Walker's post-procedure course has been marked by severe pain and discomfort, including, but not limited to, irregular menstrual periods, abdominal pain, pelvic pain, back pain, dyspareunia, dental issues, severe migraines, chronic fatigue, dizziness, memory issues and a metallic taste in her mouth. Before Essure®, she had not experienced this combination of symptoms, and she had no problem going about her daily life.

881. Since undergoing the Essure® procedure, Plaintiff Walker has repeatedly sought treatment for her symptoms from various medical providers in Pleasant Grove, Utah and Provo, Utah, but none of her treating physicians were able to determine their cause.

882. Plaintiff Walker still has the Essure® device surgically implanted.

883. Plaintiff Walker is unable to wear fake or "costume" jewelry which often contain nickel due to skin irritation.

884. Plaintiff Walker did not realize that she had a legal remedy due to her injuries from Essure® until she saw a legal advertisement describing symptoms like hers which were also being experienced by thousands of other women who had been implanted with the Essure® device. It was at this time that she truly understood that her symptoms were related to Essure® and the legal options available to her.

RR. RACHEL SIMPSON

885. Plaintiff Simpson is thirty (30) years old and resides in Aurora, Arapahoe County, Colorado.

1. Initial Essure® Procedure:

886. On or around May 23, 2013, Plaintiff Simpson underwent the Essure® procedure at Pinnacle Women's Healthcare in Parker, Colorado.

887. Jillian Tyler, MD, implanted the Essure[®] device in Plaintiff Simpson who was only twenty-five (25) years old at the time of her sterilization procedure.

888. Plaintiff Simpson was directed toward Essure[®] by her providers. She was told that Essure[®] was a quick procedure with little-to-no downtime.

2. Post Essure[®] Procedure Condition and Treatment:

889. Plaintiff Simpson's post-procedure course has been marked by severe pain and discomfort, including, but not limited to, irregular and heavy menstrual periods, pelvic pain, abdominal pain, dyspareunia, and hair loss. Before Essure[®], Plaintiff Simpson had not experienced this combination of symptoms and she had no problem with going about her daily life.

890. Since undergoing the Essure[®] procedure, Plaintiff Simpson repeatedly sought treatment for her symptoms, but no physician was able to determine the cause.

891. On or around June 14, 2013, Plaintiff Simpson presented to Dr. Tyler with complaints of ongoing pelvic pain and vaginal bleeding.

892. On or around August 22, 2013, Plaintiff Simpson presented to Mary Ann Egelston WHCNP/NCMP with complaints of prolonged vaginal bleeding, specifically, that she "only had one week of not having a period since Essure[®] was implanted." She was prescribed Provera to help manage her bleeding.

893. Also, on or around August 22, 2013, Plaintiff Simpson's physician, Dr. Pastrana, requested a consult with Katherine Weber, MD, as the Plaintiff was experiencing fatigue and hair loss for a few months. She also complained of tremors, insomnia and anxiety. She was diagnosed with hyperthyroidism.

894. On or around February 25, 2015, Plaintiff Simpson presented to Kaiser Permanente-Denver ("KPD") complaining of pelvic pain, pain during intercourse and cramping

“on and off for months.” She reported the pain is so severe at times that she has trouble standing and walking.

895. On or around March 27, 2015, Plaintiff Simpson presented to KPD with complaints of a migraine, stomach pain and a history of menstrual bleeding two weeks out of the four—with heavy flow. She was assessed with menorrhagia.

896. On or around April 9, 2015, Plaintiff Simpson returned to KPD inquiring about having Essure[®] removed. She reported heavy vaginal bleeding and having periods five to nine days long with clots.

897. Plaintiff Simpson’s symptoms have not resolved and she still has the Essure[®] device implanted.

898. Plaintiff Simpson did not realize that she had a legal remedy due to her injuries from Essure[®] until she saw a legal advertisement, on or about September 7, 2016, describing symptoms like hers which were also being experienced and suffered by thousands of other women who had been implanted with the Essure[®] device. It was at this time that she truly understood that her symptoms were related to Essure[®] and the legal options available to her.

SS. DONNA BAEZA

899. Plaintiff Baeza is twenty-nine (29) years old and resides in Colorado Springs, El Paso County, Colorado.

1. Initial Essure[®] Procedure:

900. Upon information and belief, sometime in or around 2014, Plaintiff Baeza underwent the Essure[®] procedure at UHealth Women’s Care Clinic in Colorado Springs, Colorado. Deborah Lasley, MD implanted the Essure[®] device in Plaintiff Baeza.

901. Plaintiff Baeza was directed toward Essure[®] by her providers. It was her understanding that Essure[®] was the safest form of sterilization available, did not require general anesthesia and could be performed in the doctor's office, contrary to tubal ligation.

2. Post Essure[®] Procedure Condition and Treatment:

902. Plaintiff Baeza's post-procedure course has been marked by severe pain and discomfort, including, but not limited to, irregular menstrual cycles, abdominal cramping, pelvic pain, weight gain, severe migraines, chronic bacterial vaginosis, chronic fatigue, vertigo and forgetfulness. Before Essure[®], she had not experienced this combination of symptoms and she had no problem going about her daily life.

903. Since undergoing the Essure[®] procedure, Plaintiff Baeza repeatedly sought treatment for her symptoms in Colorado Springs, Colorado.

904. Upon information and belief, Plaintiff Baeza underwent a HSG exam following her implant procedure.

905. Upon further information and belief, sometime in or around October 2017, Dr. Lasley recommended a hysterectomy with removal of the Essure[®] device to treat Plaintiff Baeza's irregular cycles and pelvic pain as she had been complaining of pain since the implant three years prior.

906. Sometime in or about October 2017, Plaintiff Baeza underwent a hysterectomy with removal of the Essure[®] device performed by Dr. Lasley at UCHealth Memorial Hospital in Colorado Springs, Colorado.

907. Despite suffering from these symptoms for over three years, Plaintiff Baeza's symptoms largely resolved only after removal of her Essure[®] device.

908. Plaintiff Baeza is unable to wear fake or "costume" jewelry which often contain nickel due to skin irritation.

909. Until the removal, neither she nor her doctors could clearly correlate her problems as being associated with the device. After the removal, the cause of her symptoms became obvious due to their resolution.

TT. CHRISTINE SCHMIDT

910. Plaintiff Schmidt is forty-seven (47) years old and resides in Belleville, St. Clair County, Illinois.

1. Initial Essure® Procedure:

911. On or around July 13, 2010, Plaintiff Schmidt underwent the Essure® procedure and a MiniArc suburethral sling procedure and right labioplasty under general anesthesia at Memorial Hospital in Belleville, Illinois.

912. William Chadwick, MD, implanted the Essure® device in Plaintiff Schmidt.

913. Plaintiff Schmidt was directed toward Essure® by her providers. She was told it was a less invasive procedure that did not require an incision.

2. Post Essure® Procedure Condition and Treatment:

914. Plaintiff Schmidt's post-procedure course has been marked by severe pain and discomfort, including, but not limited to, irregular and heavy menstrual periods, pelvic pain, abdominal pain, low back pain, bloating, hives and rashes, joint pain, chronic fatigue, memory loss and dizziness. Before Essure®, she had not experienced this combination of symptoms, and she had no problem with going about her daily life.

915. Since undergoing the Essure® procedure, Plaintiff Schmidt repeatedly sought treatment for her symptoms.

916. On or around August 18, 2014, Plaintiff Schmidt presented to Eric Strand, MD, with complaints of fatigue, irregular heartbeat, abdominal pain, pelvic pain, painful intercourse,

joint pain, muscle weakness, rashes/hives, dizziness, loss of balance, diarrhea, constipation, blood in stool, depression, anxiety and forgetfulness.

917. On or around September 8, 2014, Plaintiff Schmidt presented to Dr. Strand with complaints of heavy menses accompanied by cramping and “having to change both clothing and sheets/pajamas.” A transvaginal and transabdominal ultrasound was performed and showed free fluid visible with the largest pool measuring 18 mm x 34 mm and indicates “[t]wo slightly echogenic areas... seen at the cornual regions of the uterus that may represent the Essure but visualization was suboptimal.”

918. Plaintiff Schmidt also underwent an endometrial biopsy during her September 8, 2014, office visit with Dr. Strand. The pathology report indicates “fragments consistent with endometrial polyp”. She was diagnosed with menorrhagia and dysmenorrhea.

919. On or around November 22, 2014, Plaintiff Schmidt underwent a hysteroscopy, dilation & curettage with Novasure endometrial ablation due to her heavy periods and dysmenorrhea. The procedure was performed by Dr. Strand at Barnes Jewish Hospital in St. Louis, Missouri. The operative findings noted, “no visible polyp.”

920. Sometime in or around 2015, Plaintiff Schmidt presented to Robert Schneider, MD, with complaints of joint pain. She was diagnosed with fibromyalgia and osteoarthritis.

921. On or around January 7, 2016, Plaintiff Schmidt again presented to Dr. Strand with complaints of severe stabbing and cramping radiating to her left thigh and lower back. Plaintiff Schmidt described the pain as “waves of stabbing” like she is “in labor.”

922. On or around January 15, 2016, Plaintiff Schmidt underwent a transvaginal and transabdominal ultrasound for her dysmenorrhea after ablation. The report noted, “[t]here is a small volume of fluid in the fundal aspect of the endometrial cavity... The Essure is not visualized.” Simple cysts were also noted on both ovaries.

923. On or around January 30, 2017, Plaintiff Schmidt presented to John Daniels, MD, complaining of contraction-like cramping during her menses. Abdominal x-rays were performed and noted, “there are two Essure occlusion devices, which overlie the expected position of the fallopian tubes.”

924. On or around December 15, 2017, Plaintiff Schmidt presented to Dr. Strand for a consultation for a hysterectomy and bilateral salpingectomy to treat post-ablation vaginal bleeding. She reported that she continued to have severe contraction pain every month and suffered bleeding similar to that she experienced prior to the 2015 ablation procedure.

925. Upon information and belief, Plaintiff Schmidt is currently scheduled to undergo a hysterectomy and bilateral salpingectomy to treat post-ablation vaginal bleeding on or around August 7, 2018 in St. Louis, Missouri.

926. Plaintiff Schmidt’s symptoms have not resolved as she still has the Essure® device implanted.

927. Plaintiff Schmidt is unable to wear fake or “costume” jewelry which often contain nickel due to skin irritation.

928. Plaintiff Schmidt did not realize that she had a legal remedy due to her injuries from Essure until she saw a legal advertisement describing symptoms like hers which were also being experienced and suffered by thousands of other women who had been implanted with the Essure® device. It was at this time that she truly understood that her symptoms were related to Essure and the legal options available to her.

UU. AMANDA SULLIVAN

929. Plaintiff Sullivan is thirty-two (32) years old and resides in Colorado Springs, El Paso County, Colorado.

1. Initial Essure® Procedure:

930. Upon information and belief, sometime in or around February 2011, Plaintiff Sullivan underwent the Essure® procedure under general anesthesia at Women's Associates, P.C. in Colorado Springs, Colorado. Lisa Hovenga, MD, implanted the Essure® device in Plaintiff Sullivan.

931. Further, Plaintiff Sullivan was not informed that the Essure® procedure as marketed was not intended to take place under general anesthesia and that the balance of risks and benefits of Essure® versus tubal ligation was unfavorable to Essure® under such circumstances.

932. Plaintiff Sullivan was directed toward Essure® by her providers. It was her understanding that Essure® was less invasive than tubal ligation.

2. Post Essure® Procedure Condition and Treatment:

933. Plaintiff Sullivan's post-procedure course has been marked by increasingly severe pain and discomfort, including, but not limited to, irregular and heavy menstrual periods, pelvic pain, abdominal pain, dyspareunia, weight gain, bloating, dental issues, hair loss, memory loss, dizziness and a metallic taste in her mouth. Before Essure®, she had not experienced this combination of symptoms, and she had no problem with going about her daily life.

934. Upon information and belief, Plaintiff Sullivan had a HSG exam.

935. Since undergoing the Essure® procedure, Plaintiff Sullivan has repeatedly sought treatment for her symptoms, but none of her treating physicians were able to determine their cause.

936. Sometime on or around December 12, 2013, Plaintiff Sullivan underwent a partial hysterectomy and removal of the Essure® device at Women's Associates P.C. in Colorado Springs, Colorado.

937. Plaintiff Sullivan is unable to wear fake or "costume" jewelry which often contain nickel due to skin irritation.

938. Plaintiff Sullivan did not realize that she had a legal remedy due to her injuries from Essure[®] until she saw a legal advertisement, sometime on or about September 8, 2016, describing symptoms like hers which were also being experienced by thousands of other women who had been implanted with the Essure[®] device. It was at this time that she truly understood that her symptoms were related to Essure[®] and the legal options available to her.

VV. TABITHA ROSS

939. Plaintiff Ross is thirty-two (32) years old and resides in Austin, Travis County, Texas.

1. Initial Essure[®] Procedure:

940. On or around August 23, 2012, Plaintiff Ross underwent the Essure[®] procedure under general anesthesia at Austin Regional Clinic in Austin, Texas. Alinda Cox, MD, implanted the Essure[®] device in Plaintiff Ross.

941. Further, Plaintiff Ross was not informed that the Essure[®] procedure as marketed was not intended to take place under general anesthesia and that the balance of risks and benefits of Essure[®] versus tubal ligation was unfavorable to Essure[®] under such circumstances.

942. Plaintiff Ross was directed toward Essure[®] by her providers. It was her understanding that Essure[®] had a shorter recovery period than a bilateral tubal ligation.

2. Post Essure[®] Procedure Condition and Treatment:

943. Plaintiff Ross' post-procedure course has been marked by severe pain and discomfort, including, but not limited to, irregular and heavy menstrual periods, pelvic pain, abdominal pain, weight gain, hair loss, rashes and hives, joint pain, memory loss and a subsequent pregnancy that resulted in a miscarriage. Before Essure[®], she had not experienced this combination of symptoms, and she had no problem going about her daily life.

944. Since undergoing the Essure[®] procedure, Plaintiff Ross has repeatedly sought treatment for her symptoms from various medical providers in Austin, Texas, but none of her treating physicians were able to determine their cause.

945. Plaintiff Ross still has the Essure[®] device surgically implanted.

946. Plaintiff Ross did not realize that she had a legal remedy due to her injuries from Essure[®] until she saw a legal advertisement, sometime on or about September 7, 2017, describing symptoms like hers which were also being experienced by thousands of other women who had been implanted with the Essure[®] device. It was at this time that she truly understood that her symptoms were related to Essure[®] and the legal options available to her.

WW. BOBBY HERNANDEZ

947. Plaintiff Hernandez is thirty-four (34) years old and resides in Abilene, Taylor County, Texas.

1. Initial Essure[®] Procedure:

948. On or around September 13, 2013, Plaintiff Hernandez underwent the Essure[®] procedure in Abilene, Taylor County, Texas.

949. Whitney Mascorro, MD, implanted the Essure[®] device in Plaintiff Hernandez.

950. Plaintiff Hernandez was directed toward Essure[®] by her providers. It was her understanding that Essure[®] was as safe or safer than a bilateral tubal ligation.

2. Post Essure[®] Procedure Condition and Treatment:

951. Sometime in or around December 2013, Plaintiff Hernandez underwent a HSG exam which demonstrated bilateral tubal occlusion.

952. Plaintiff Hernandez's post-procedure period has been marked by painful menstrual cycles, abdominal pain, abdominal bloating, brittle teeth, hair loss, chronic fatigue, joint pain,

weight gain and blurred vision. Before Essure®, she had not experienced this combination of symptoms and she had no problem going about her daily life.

953. Over the course of the following three years, Plaintiff Hernandez repeatedly sought treatment for her symptoms, but none of her treating physicians were able to determine their cause.

954. It was not until sometime in or around August 2016, when Plaintiff Hernandez began to research the Essure® device and her symptoms, that she realized the same symptoms were also being experienced and suffered by thousands of other women who had been implanted with the Essure® device. It was at this time that she truly understood that her symptoms could be related to Essure®.

955. Thereafter, Plaintiff Hernandez consulted with her primary care physician, Sandra Flores, MD, and her OB/GYN, Robert Ogdee, MD, about having the Essure® device removed.

956. On or around March 26, 2017, Plaintiff Hernandez underwent a hysterectomy with bilateral salpingectomy and Essure® removal performed by Dr. Ogdee at the Abilene Regional Medical Center in Abilene, Taylor County, Texas.

957. After the removal of the Essure® device many of Plaintiff Hernandez's symptoms resolved, and the cause of her health problems became obvious, due to their resolution.

XX. SHABRETA TERRELL

958. Plaintiff Terrell is thirty-nine (39) years old and resides in Mansfield, DeSoto Parish, Louisiana.

1. Initial Essure® Procedure:

959. Upon information and belief, sometime in or around June 2012, Plaintiff Terrell underwent the Essure® procedure at University Health Shreveport in Shreveport, Louisiana.

960. Plaintiff Terrell was directed toward Essure® by her providers. It was her understanding that Essure® was safer and less invasive than traditional tubal ligation.

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2. Post Essure® Procedure Condition and Treatment:

961. Plaintiff Terrell's post-procedure course has been marked by severe pain and discomfort, including, but not limited to, heavy and irregular menstrual cycles, severe abdominal cramping, pelvic pain, lower back pain, weight gain, dental issues, rashes, hair loss, joint pain, frequent urinary tract infections, chronic fatigue, memory loss, a metallic taste in her mouth, and severe migraines. Before Essure®, she had not experienced this combination of symptoms, and she had no problem going about her daily life.

962. Upon information and belief, Plaintiff Terrell underwent a HSG exam following her implant procedure.

963. Upon further information and belief, since undergoing the Essure® procedure, Plaintiff Terrell repeatedly sought treatment for her symptoms. Her treating physicians did not indicate that there was a causal relationship between her post-Essure® implantation symptomatology and the Essure® device until February 2018.

964. Plaintiff Terrell still has the Essure® device surgically implanted.

965. Plaintiff Terrell did not realize that she had a legal remedy due to her injuries from Essure® until she saw a legal advertisement, on or about August 30, 2017, describing symptoms like hers which were also being experienced by thousands of other women who had been implanted with the Essure® device. It was at this time that she truly understood that her symptoms were related to Essure and the legal options available to her.

YY. NANCY RIVERA

966. Plaintiff Rivera is forty-two (42) years old and resides in Joliet, Kendall County, Illinois.

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1. Initial Essure® Procedure:

967. Upon information and belief, sometime in or around November 2002, Plaintiff Rivera underwent the Essure® procedure under general anesthesia at Advocate Christ Medical Center in Oak Lawn, Illinois.

968. Further, Plaintiff Rivera was not informed that the Essure® procedure as marketed was not intended to take place under general anesthesia and that the balance of risks and benefits of Essure® versus tubal ligation was unfavorable to Essure® under such circumstances.

969. Plaintiff Rivera was directed toward Essure® by her providers. It was her understanding that Essure® was safer with a shorter recovery period than a bilateral tubal ligation.

2. Post Essure® Procedure Condition and Treatment:

970. Plaintiff Rivera's post-procedure course has been marked by severe pain and discomfort, including, but not limited to, irregular and heavy menstrual periods, pelvic pain, abdominal pain, dental issues, severe headaches, chronic fatigue, skin issues, and hair loss. Before Essure®, she had not experienced this combination of symptoms and she had no problem going about her daily life.

971. Since undergoing the Essure® procedure, Plaintiff Rivera repeatedly sought treatment for her symptoms from various medical providers in Chicago, Illinois; Joliet, Illinois; Chicago Ridge, Illinois; and Bridgeview, Illinois, but none of her treating physicians were able to determine their cause.

972. On or around February 5, 2016, Plaintiff Rivera underwent various x-rays of her hip and pelvis due to joint pain she was experiencing. The radiology report notes the "Essure wires are seen in the pelvis."

973. On or around October 19, 2016, Plaintiff Rivera presented to her primary care provider, Dr. Dharmesh Patel, where she is diagnosed with acute vaginitis and prescribed medication.

974. Plaintiff Rivera still has the Essure[®] device surgically implanted.

975. Plaintiff Rivera did not realize that she had a legal remedy due to her injuries from Essure[®] until she saw a legal advertisement, sometime on or about August 24, 2016, describing symptoms like hers which were also being experienced by thousands of other women who had been implanted with the Essure[®] device. It was at this time that she truly understood that her symptoms were related to Essure[®] and the legal options available to her.

ZZ. DARRIELL CLEMENTS

976. Plaintiff Clements is thirty-eight (38) years old and resides in Union City, Fulton County, Georgia.

1. Initial Essure[®] Procedure:

977. Upon information and belief, in or around August 2010, Plaintiff Clements underwent the Essure[®] procedure at Apogee Women's Health in College Park, Georgia.

978. Anthony Adams, MD, implanted the Essure[®] device in Plaintiff Clements.

979. Plaintiff Clements was directed toward Essure[®] by her providers. It was her understanding that Essure[®] was as safe or safer than a bilateral tubal ligation as it would not require general anesthesia and could be performed in the doctor's office, contrary to a tubal ligation.

2. Post Essure[®] Procedure Condition and Treatment:

980. Plaintiff Clements' post-procedure course has been marked by severe pain and discomfort, including, but not limited to, irregular and heavy menstrual periods, pelvic pain, chronic yeast infections, chronic fatigue, weight gain, hair loss, dizziness, severe migraines and a

migrated coil. Before Essure®, she had not experienced this combination of symptoms, and she had no problem going about her daily life.

981. Upon information and belief, Plaintiff Clements had a HSG exam completed sometime in or around December 2010, which demonstrated bilateral occlusion.

982. Since undergoing the Essure® procedure, Plaintiff Clements repeatedly sought treatment for her symptoms from various medical providers in Atlanta, Georgia.

983. Upon information and belief, sometime in or around May 2016, Plaintiff Clements was referred to Emory University Hospital Midtown (“EUHM”) in Atlanta, Georgia by Dr. Adams. A pelvic ultrasound was performed which revealed that one coil had migrated.

984. Upon further information and belief, Dr. Adams recommended removal of the Essure® coils sometime in or around June 2016 due to the migrated coil.

985. On or around April 24, 2018, Plaintiff Clements underwent a CT scan which further revealed that both Essure® coils had migrated out of her fallopian tubes.

986. Plaintiff Clements still has the Essure® devices surgically implanted.

987. Plaintiff Clements did not realize that she had a legal remedy due to her injuries from Essure® until she saw a legal advertisement, sometime in or around March 2017, describing symptoms like hers which were also being experienced by thousands of other women who had been implanted with the Essure® device. It was at this time that she truly understood that her symptoms were related to Essure® and the legal options available to her.

AAA. AMY RUTAN

988. Plaintiff Rutan is thirty-eight (38) years old and resides in Lathrop, San Joaquin County, California.

1. Initial Essure® Procedure:

989. Upon information and belief, in or around 2008, Plaintiff Rutan underwent the Essure® procedure at Kaiser Permanente in Pleasanton, California.

990. Karen Simpson, MD, implanted the Essure® device in Plaintiff Rutan.

991. Plaintiff Rutan was directed toward Essure® by her providers. It was her understanding that Essure® was as safe or safer than a bilateral tubal ligation.

2. Post Essure® Procedure Condition and Treatment:

992. Plaintiff Rutan's post-procedure course has been marked by increasingly severe pain and discomfort, including, but not limited to, menorrhagia, dysmenorrhea, pelvic pain, back pain, dyspareunia, abdominal bloating, weight gain, severe dental issues, skin rashes, hair loss, joint pain, severe migraines, chronic bacterial vaginosis, a metallic taste in her mouth, and memory loss. Before Essure®, she had not experienced this combination of symptoms, and she had no problem with going about her daily life.

993. Upon information and belief, Plaintiff Rutan had a HSG exam completed at Kaiser Permanente in Martinez, California.

994. Plaintiff Rutan first sought treatment for her symptoms sometime in or around December 2015.

995. Since undergoing the Essure® procedure, Plaintiff Rutan repeatedly sought treatment for her symptoms from various medical providers in Martinez, California; Stockton, California; Tracy, California; and Pleasanton, California, but none of her treating physicians were able to determine their cause.

996. Plaintiff Rutan still has the Essure® device surgically implanted.

997. Plaintiff Rutan did not realize that she had a legal remedy due to her injuries from Essure® until she saw a legal advertisement describing symptoms like hers which were also being

experienced and suffered by thousands of other women who had been implanted with the Essure[®] device. It was at this time that she truly understood that her symptoms were related to Essure[®] and the legal options available to her.

BBB. LINDA SANTE

998. Plaintiff Sante is fifty-three (53) years old and resides in Pittsburgh, Allegheny County, Pennsylvania.

1. Initial Essure[®] Procedure:

999. On or around December 15, 2003, Plaintiff Sante underwent the Essure[®] procedure at Forbes Hospital in Monroeville, Allegheny County, Pennsylvania.

1000. Mark Rubino, MD, implanted the Essure[®] device in Plaintiff Sante.

1001. Further, Plaintiff Sante was not informed that the Essure[®] procedure as marketed was not intended to take place under general anesthesia and that the balance of risks and benefits of Essure[®] versus tubal ligation was unfavorable to Essure[®] under such circumstances.

1002. Plaintiff Sante was directed toward Essure[®] by her providers as an option for permanent sterilization as she was advised that she was a good candidate for this procedure.

2. Post Essure[®] Procedure Condition and Treatment:

1003. Plaintiff Sante's post-procedure course has been marked by increasingly severe pain and discomfort, including chronic abdominal/pelvic pain, heavy bleeding, vaginal discharge, joint pain, back pain, neck pain, urinary incontinence, headaches, peripheral neuropathy, swelling of hands, feet and legs, heart palpitations, night sweats, numbness in head and face, hair loss, memory loss, a metallic taste in her mouth and various skin rashes/irritations. Before Essure[®], she never experienced this combination of symptoms prior to undergoing the Essure[®] procedure.

1004. Plaintiff Sante subsequently sought treatment for her symptoms from Dr. Mark Rubino, Dr. Amer Arkhrass, Dr. Simin Khavandgar, Dr. Terence Starz and various other

physicians located within Pennsylvania. Despite being subsequently diagnosed with fibromyalgia and possibly multiple sclerosis, her treating physicians have been unable to determine their etiology and have been unable to resolve her symptoms.

1005. Upon information and belief, Plaintiff Sante underwent a partial hysterectomy sometime in or around July 2011 which included removal of the Essure[®] device.

1006. Due to ongoing symptomatology following removal, Plaintiff Sante underwent an x-ray of her abdomen on or about June 19, 2018. The addendum to the report noted “a punctate radiodensity seen overlying the left hemipelvis.” While the radiologist noted that this “does not appear to represent a typical Essure device,” Dr. Rubino advised her that a “negligible piece” of the Essure[®] device has possibly been retained.

1007. Plaintiff Sante is unable to wear fake or “costume” jewelry which often contain nickel due to skin irritation.

1008. Plaintiff Sante did not realize until she saw a legal advertisement, sometime in or around July 2018, that her symptoms were also being experienced and suffered by thousands of other women who had been implanted with the Essure[®] device. It was at this time, she truly understood that her symptoms were related to Essure[®] and the legal options available to her.

VIII. AGENCY, ALTER-EGO, JOINT VENTURE, AND CONSPIRACY

1009. At all times herein mentioned, the Defendants were fully informed of the actions of their agents, representatives, contractors, and/or employees, and thereafter, no officer, director or managing agent of the Defendants repudiated those actions. The failure to repudiate constituted adoption and approval of said actions, and all Defendants and each of them thereby ratified those actions.

1010. At all times mentioned herein, there existed (and still exists) a unity of interest between certain Defendants and other certain Defendants such that any individuality and

separateness between the certain Defendants has ceased, and these Defendants are the alter-egos of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege, sanction a fraud, and/or promote injustice.

1011. Each of the Bayer Defendants herein expressly or impliedly agreed to work with and assist each other Defendant and unnamed parties, toward the common purpose of promoting, recommending, and selling Essure® and toward the common interest of pecuniary gain.

1012. Each of the Bayer Defendants herein performed the acts and omissions described herein in concert with the other Bayer Defendants herein and/or pursuant to a common design with the other Defendants herein.

1013. Each of the Bayer Defendants herein knew the acts and omissions of the other Bayer Defendants herein constituted a breach of duty, and yet, each Bayer Defendant provided each other Bayer Defendant substantial assistance and/or encouragement.

1014. Each of the Bayer Defendants herein provided substantial assistance to the other Bayer Defendants herein in accomplishing the intentional and tortious conduct described herein, and each Bayer Defendants' conduct, even when separately considered, constitutes a breach of duties owed to the Plaintiffs.

1015. At all times herein mentioned, each of the Bayer Defendants were engaged in the business of and/or were a successor in interest to and/or affiliated with/associated with/indistinguishable from entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, advertising for sale, and/or selling Essure® device for use by the Plaintiffs and the Plaintiffs' physicians. As such, each of the

Bayer Defendants is individually, as well as jointly and severally, liable to the Plaintiffs for the Plaintiffs' damages.

1016. The conduct of the Defendants herein caused the Plaintiffs' harm as described herein. The Plaintiffs' harm is not in any way attributable to any fault of the Plaintiffs. Uncertainty may exist regarding which Defendant(s) and/or combination of Defendants caused the Plaintiffs' harm. The Defendants possess superior knowledge and information regarding which Defendant(s) and/or combination of Defendants caused the Plaintiffs' injuries.

1017. Thus, the burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by the Plaintiffs.

1018. Due to the above, each Cause of Action named below is asserted against each Defendant herein, jointly and severally, even if each and every Defendant herein is not specifically identified as to each and every count.

IX. PLAINTIFFS ARE ENTITLED TO PUNITIVE DAMAGES

1019. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

1020. As a result of Conceptus' and Bayer's oppression, fraudulent concealment, wantonness, malice, and reckless disregard for Plaintiffs' safety, Plaintiffs are entitled to punitive or exemplary damages to the fullest extent necessary as plead in detail below.

X. CLAIMS FOR RELIEF

1021. No action alleged below depends on the violation of federal law as an element of the cause of action. Instead, by violating federal duties, parallel state laws were violated, as those federal duties are not different from or in addition to parallel state duties. Plaintiffs are alleging that the Bayer Defendants' conduct that violates these federal regulations, as well as the PMA obtained for Essure®, also violates parallel state laws.

FIRST CAUSE OF ACTION – Negligence: Failure to Warn

***Stengel*¹²⁸ - Failure to Warn**
Restat. 2d of Torts, § 388 cmt. n¹²⁹

1022. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

A. CONCEPTUS AND BAYER HAD A DUTY TO REPORT ADVERSE EVENTS TO THE FDA UNDER FEDERAL LAW.

1023. Conceptus and Bayer at all times herein were medical device manufacturers and subject to the Medical Device Reporting (MDR) regulations under 21 C.F.R. § 803.

1024. As discussed above, Conceptus and Bayer, through their employees and agents, had a federal duty to “report deaths and serious injuries that a device [such as Essure[®]] has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports” of these Adverse Events (“AEs”) related to Essure[®] to the FDA. *See* 21 C.F.R. § 803.1.

1025. “These reports help [the FDA] to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.” *Id.*

1026. As set out in detail above, Conceptus and Bayer failed to timely and accurately report to the FDA these adverse events reasonably associated with the use of their medical device,

¹²⁸ *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013). *Stengel* was followed in the context of an Essure[®] case by the United States District Court for the Eastern District of Pennsylvania, in *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Pa. 2016) (“Thus, while Bayer is correct that Plaintiffs have not pointed to a case that explicitly imposes a duty to file adverse reports with the FDA, Plaintiffs have cited to Pennsylvania law that is essentially indistinguishable from the Arizona law that the Ninth Circuit found sufficient to create a parallel [**86] and independent state claim in *Stengel*. Accordingly, we follow the reasoning of the *en banc* decision in *Stengel* and conclude that Plaintiffs' failure to warn claim, as stated, is not expressly preempted, at least insofar as it is premised upon Bayer's alleged failure to report adverse events to the FDA. We therefore deny Bayer's Motion insofar as it seeks dismissal of Plaintiffs' negligent failure to warn claim in Count XII.”).

¹²⁹ Adopted by *Phillips v. A.P. Green Refractories Co.*, 630 A.2d 874 (Pa. Super. Ct. 1993).

Essure[®]. The Defendants' failure to report was in violation of their duties under the PMA, FDCA and various federal regulations (e.g. 21 C.F.R. § 803.1-.58, 21 C.F.R. § 814.82).

1. Conceptus and Bayer Had a Federal Duty to Report AEs Under the "Conditions for Approval" of Essure[®]'s PMA.

1027. Class III devices, such as Essure[®], are required to go through the PMA process to provide reasonable assurance of their safety and effectiveness.

1028. The federal government has established requirements applicable to Essure[®] in part because of the PMA process established specific requirements applicable to the device, including Conceptus' and Bayer's duties under the "Conditions for Approval" to Essure[®]'s PMA to issue a CBE (as explained in Paragraphs above) or to seek a PMA supplement to change Essure[®]'s labeling "when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification,"¹³⁰ described in ¶159(C) above. These Conditions for Approval require manufacturers, like Conceptus and Bayer, to take the steps to change their labeling under such circumstances in order to assure that the devices "are not adulterated or misbranded and are safe and effective for their intended use."¹³¹

1029. Further, the FDA may impose post-approval requirements, including a "[c]ontinuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use."¹³²

¹³⁰ See

<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm050467.htm> (last updated November 14, 2017).

¹³¹ These requirements are identical to that required of a drug manufacturer in the same or similar circumstances. See also 21 C.F.R. § 814.80, which requires that a device "not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device."

¹³² 21 C.F.R. § 814.82.

1030. The FDA did impose these post-approval requirements in the Essure[®] PMA, which stated that in order for the FDA to be continually assured of the safety and effectiveness of the device, an “Adverse Reaction Report” or “Device Defect Report” should be filed within ten (10) days of Bayer and Conceptus receiving knowledge or information of, in part, “[a]ny adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and: a. has not been addressed by the device’s labeling; or b. has been addressed by the device’s labeling but is occurring with unexpected severity or frequency.”

1031. Instead, and in violation of 21 C.F.R. § 820.198, 21 C.F.R. § 803.3 and the Essure[®] PMA “Conditions of Approval,” Conceptus and Bayer (1) failed to appropriately respond to adverse incident reports, including but not limited to, reports of device migration outside of the fallopian tubes and/or device fracture/breakage, which strongly indicated the Essure[®] device was malfunctioning or otherwise not responding to its Design Objective Intent, which was to remain permanently in Plaintiffs’ fallopian tubes, and (2) Conceptus and Bayer continued to place Essure[®] into the stream of interstate commerce when they knew, or should have known, that the Essure[®] device was malfunctioning or otherwise not responding to its Design Objective Intent.

2. Conceptus and Bayer had a Duty to Report Adverse Events Under 21 C.F.R. § 803.50, § 814.82.

1032. As described above, the obligations of a medical device manufacturer do not end with FDA's Premarket Approval ("PMA") process. Under federal law a medical device manufacturer has a continuing duty to monitor their product after premarket approval and to discover and report to the FDA any complaints about the product’s performance and any adverse health consequences of which it became aware and that are or may be attributable to the product.

1033. As detailed above, this includes information the manufacturer receives or otherwise becomes aware of, from any source, that reasonably suggests that a device may have caused or

contributed to death or serious injury; or has malfunctioned in a manner that would likely “cause or contribute to a death or serious injury” if it recurred.¹³³

1034. As discussed in detail above, Conceptus and Bayer failed to report and/or timely report adverse events, including but not limited to, complaints of device migration, device fracture/breakage, perforation, heavy menstrual cycle bleeding, and long-term chronic pain, all of which are serious injuries or may lead to a serious injury.

1035. As detailed above, the FDA discovered the overwhelming number of Essure® adverse events only after women were no longer forced to report their problems directly to Conceptus or Bayer (or indirectly through healthcare providers) and had the option to use the “MedWatcher App” and report directly to the FDA.

1036. Between 2002 and through to 2016, the FDA received approximately 14,919 medical device reports (MDRs) related to safety problems with the device.¹³⁴ In 2017, the FDA received 11,854 reports.¹³⁵ In total, the FDA has received 26,773 MDRs from 2002 through 2017.

1037. The most frequent MDRs regarding patient problems were as follows: “pain/abdominal pain (21,215), heavier menses/menstrual irregularities (9,846), headache (7,231), fatigue (5,842), and weight fluctuations (4,970). Most of the reports received listed multiple patient problems in each report. The most frequent device problems reported were patient-device incompatibility example, possible nickel allergy (4,481), migration of the device or device component (2,936), dislodged or dislocated device (1,356), device breakage (1,044), device

¹³³ 21 C.F.R. § 803.50(a); *see also* 21 U.S.C. § 360i(a) (further detailing the post approval reporting requirements applicable to device manufacturers).

¹³⁴ *See*

<https://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/essurepermanentbirthcontrol/ucm452254.htm> (last updated March 7, 2018).

¹³⁵ *See id.*

operating differently than expected (947), device difficult to remove (331), device difficult to insert (317), and malposition of the device (279).”¹³⁶

1038. More than 90% of the MDRs received in 2017 mentioned issues involving potential device removal.

1039. Defendants’ failure to report adverse events is further evidenced by the 2011 FDA Form 483.¹³⁷

1040. Conceptus and Bayer failed to adequately disclose to the FDA under its regulations Adverse Events which clearly impacted the safety, effectiveness, and foreseeable risk, and revealed increased risks and dangers of Essure® of which these manufacturers were informed after Essure®’s PMA approval.

3. Conceptus and Bayer had a Federal Duty to Report New Clinical Investigations and/or Scientific Studies under 21 C.F.R. § 814.84(b)(2).

1041. As discussed in detail above, Conceptus and Bayer failed to report new clinical investigations and/or scientific studies concerning the Essure® device about which Conceptus and Bayer knew or reasonably should have known, including but not limited to the Cornell study, the article published in the online medical journal Conception, and the eight (8) articles describing twelve (12) cases of Essure® abdominal migration published between January 2002 and December 2013 that were never reported to the FDA.

4. Conceptus and Bayer had Continuing Duties Under 21 C.F.R. §§ 820.198, 820.300, 820.700 & 820.100 to Discover, Investigate and Respond to Adverse Events.

1042. Federal law also requires certain procedures be put into place to discover and address adverse events and their causes. Conceptus and Bayer violated these requirements as

¹³⁶ See *id.*

¹³⁷ See <http://3qg8x72qeng62erdph228vql.wpengine.netdna-cdn.com/wp-content/uploads/Conceptus-2011-483.pdf> (last visited January 31, 2018).

follows:

- **21 C.F.R. § 820.100:** Conceptus and Bayer: (1) failed to routinely analyze complaints and other sources of quality data to identify existing and potential causes of nonconforming products or other quality problems and failed to use appropriate statistical methodology to detect recurring quality problems, including but not limited to, complaints of perforation, device migration, and/or device fracture/breakage; (2) failed to investigate the cause of nonconformities relating to product, processes, and the quality system; (3) failed to identify the action(s) needed to correct and prevent recurrence of such nonconforming product and other quality problems; and (4) failed to take any and all Corrective and Preventive Actions (“CAPA”) necessary to address non-conformance and other internal quality control issues;
- **21 C.F.R. § 820.198:** Conceptus and Bayer had duties to receive, review, investigate, evaluate, record and report adverse events. “[R]ecords of investigation under this paragraph shall include a determination of: (a) [w]hether the device failed to meet specifications; (b) [w]hether the device was being used for treatment or diagnosis; and (c) [t]he relationship, if any, of the device to the reported incident or adverse event.” Conceptus and Bayer failed to comply with these quality control standards, and failed to establish and maintain procedures for implementing CAPAs in response to, *inter alia*, complaints of, but not limited to, device migration, device fracture/breakage, perforation, heavy menstrual cycle bleeding, long-term chronic pain, and other quality problems associated with the Essure® device; and failed to appropriately respond to adverse incident reports, including but not limited to, reports of device migration outside of the fallopian tubes and/or device fracture/breakage, which strongly indicated the Essure® device was malfunctioning or otherwise not responding to its Design Objective Intent, which was to remain permanently in Plaintiffs’ fallopian tubes;
- **21 C.F.R. § 820.30:** Conceptus and Bayer failed to establish and maintain procedures for validating the device design, including testing of production units under actual or simulated use conditions, creation of a risk plan, and conducting risk analyses, upon obtaining knowledge of device failures including but not limited to perforation, device migration, and/or device fracture/breakage; and,
- **21 C.F.R. § 820.70:** Conceptus and Bayer failed to establish Quality Management Systems (“QMS”) procedures to assess potential causes of non-conforming products, including but not limited to device migration, device fracture/breakage, and/or latent manufacturing defects, and other quality problems with the Essure® device.

5. Conceptus and Bayer had a Federal Duty to Modify Essure®’s Labeling under 21 C.F.R. § 803.39(a).

1043. Any changes the manufacturer believes could affect the safety and effectiveness of the device must be submitted via a “PMA Supplement,” to the FDA for approval under 21 C.F.R. § 803.39(a).

1044. While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, labeling changes if they effect the safety and effectiveness of the device.¹³⁸

1045. Conceptus and Bayer had a duty to submit a PMA supplement once it knew or should have known that the label approved by the FDA under the PMA approval had become inadequate, due to the multiple post-approval reports of serious adverse events associated with the use of Essure®.

1046. Due to its failure to submit a PMA supplement, the labeling originally approved by the FDA for Essure® became inadequate before the Plaintiffs' surgery and thus failed to protect the public health by failing to adequately disclose the harms, risks and benefits of Essure®.

6. Conceptus and Bayer Chose Not to Submit a "CBE" Supplement¹³⁹ under 21 C.F.R. § 803.39(d).

1047. Although most changes to the labeling of a device after premarket approval require FDA approval of a supplemental application, under the CBE regulation, a manufacturer may place into effect any change that enhances the safety of the device or the safety in the use of the device prior to the receipt of a written FDA order approving the PMA supplement, including:

[l]abeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association.¹⁴⁰

1048. Under those regulations, the manufacturer is required to notify the FDA of "Changes Being Effected" to a device's labeling.

1049. Under the FDA's CBE supplement procedure, Conceptus and Bayer could have unilaterally (without prior FDA approval) added a stronger, accurate warning to Essure® once they

¹³⁸ 21 C.F.R. § 814.39(a).

¹³⁹ In this Complaint, "CBE" refers to "Changes Being Effected" pursuant to 21 C.F.R. § 814.39 (2012).

¹⁴⁰ 21 C.F.R. § 814.39(d) (2012).

learned of the adverse events associated with the device.

1050. Conceptus and Bayer had a duty to amend and strengthen its labeling for Essure[®] once it knew or should have known that the label approved by the FDA under the PMA approval had become inadequate, due to the multiple post-PMA approval reports of serious adverse events associated with the use of Essure[®], which Bayer failed to properly report to the FDA and failed to adequately investigate. A CBE supplement would have been one way for Bayer to satisfy this federal duty.

1051. Thus, under the PMA approval, and under 21 C.F.R. § 803.39(a), Bayer was required to modify and strengthen the Essure[®] labeling and was permitted to do so without prior FDA approval.

1052. The FDA, in its website, readily advises and recognizes that such a change can be made without preapproval, and that the change is not inconsistent with any device specific regulations.¹⁴¹

1053. There is no evidence that the FDA would have rejected a CBE label change, and in fact the subsequent “Black Box Warning” and patient check-list from the FDA indicates that the FDA would have accepted any label which strengthened the safety warnings had the FDA known of all the adverse events that these Defendants had a duty to report.

1054. Due to the Defendants’ failure to strengthen its warning under a CBE or through a PMA supplement, the labeling approved by the FDA in the Essure[®] PMA became inadequate and did not disclose the harms, risks and dangers of Essure[®] which were known or should have been known through adequate investigation of adverse events by Bayer and Conceptus.

¹⁴¹ See <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm050467.htm> (last updated November 14, 2017).

A. CONCEPTUS AND BAYER HAD A DUTY TO REPORT ADVERSE EVENTS TO THE FDA UNDER PENNSYLVANIA LAW AND A DUTY TO MODIFY THE LABELING BASED ON PENNSYLVANIA LAW TO ADEQUATELY WARN PHYSICIANS AND THEIR PATIENTS.

1055. Under Pennsylvania state law, these Defendants had a parallel and identical duty to report and warn the FDA and other third parties of dangers associated with medical devices marketed for uses intended by them.¹⁴²

1056. These state law requirements provided only another reason for these Defendants to conform to their duties under federal law, FDA Regulations and PMA Conditions of Approval, detailed above.

1057. Such parallel duties were essentially identical because both required these Defendants to take the same action in order to assure the safe and effective use of their medical devices. Both required not only that serious adverse events be reported to third parties, but also that these Defendants investigate such events and determine the root cause of such events. Under Pennsylvania law, Conceptus and Bayer had a duty to warn pursuant to the Restatement 2d of Torts § 388 (1965).¹⁴³ Comment n provides that,

a supplier's duty to warn is discharged by providing information about the product's dangerous propensities *to a third person upon whom it can reasonably rely to communicate the information to the ultimate users of the product* or those who may be exposed to its hazardous effects. Restat. 2d of Torts § 388 cmt. n.¹⁴⁴

¹⁴² *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804 (E.D. Pa. Mar. 22, 2016) (citing *Phillips v. A.P. Green Refractories Co.*, 630 A.2d 874 (Pa. Super. 1993); see also *Sherk v. Daisy-Heddon, a Div. of Victor Comptometer Corp.*, 450 A.2d 615 (Pa. 1982) (a general duty of care on product manufacturers); *Gurley v. Janssen Pharms., Inc.*, 113 A.3d 283 (Pa. Super. 2015) (a cause of action for failure to warn); and Restat. 2d of Torts, § 388 cmt. n, (a contemplation that a warning to a third party, such as the FDA, can satisfy a manufacturer's duty to warn).

¹⁴³ Adopted by *Phillips v. A.P. Refractories Co.*, 630 A.2d 874 (Pa. Super. 1993); *aff'd sub nom. Phillips v. A-Best Products Co.*, 665 A.2d 1167 (Pa. 1995).

¹⁴⁴ Emphasis added. See also *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 837-38 (E.D. Pa. Mar. 22, 2016).

1058. The “learned intermediary rule,” which is generally an exception to a manufacturer’s duty to warn, cannot apply where a device manufacturer fails at its legal obligation to provide adequate warning to the health-care provider.¹⁴⁵ If the manufacturer fails to adequately warn the learned intermediary, then it may be liable to the injured patient-consumer.¹⁴⁶

1059. Conceptus’ and Bayer’s failure to report Adverse Events to the FDA resulted in the PMA-approved labeling and warnings for Essure® being inadequate, due to the additional “after-acquired” information regarding the harms, risks and benefits contained in the Adverse Events associated with Essure® that were not reported to the FDA, not available to the FDA at the time of the PMA approval and/or not adequately investigated by Conceptus and Bayer.

B. CONCEPTUS’ AND BAYER’S DUTY TO WARN UNDER PENNSYLVANIA LAW IS NOT DIFFERENT FROM OR IN ADDITION TO FEDERAL REQUIREMENTS.

1060. “State requirements are preempted under the MDA only to the extent that they are “different from, or in addition to” the requirements imposed by federal law.¹⁴⁷ Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case “parallel,” rather than add to, federal requirements.”¹⁴⁸

1061. As described above, claims for failure to warn are not preempted. “Failure to warn claims are neither expressly nor impliedly preempted by the MDA to the extent that this claim is premised on [the defendant manufacturer]’s violation of FDA regulations with respect to reporting [adverse outcomes] caused by the device.”¹⁴⁹

¹⁴⁵ *Lance v. Wyeth*, 85 A.3d 434, 457 (Pa. 2014); *see also Rosci v. Acromed, Inc.*, 669 A.2d 959 (Pa. Super. 1995).

¹⁴⁶ *Lance*, 85 A.3d at 457; *see also Gurley v. Janssen Pharms, Inc.*, 113 A.3d 283 (Pa. Super. 2015), and *Cochran v. Wyeth, Inc.*, 3 A.3d 673, 676-77 (Pa. Super. 2010), *appeal denied* 20 A.3d 1209 (Pa. 2011).

¹⁴⁷ 21 U.S.C. § 360k(a)(1).

¹⁴⁸ *Riegel v. Medtronic*, 552 U.S. 312, 330 (2008).

¹⁴⁹ *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 776 (5th Cir. 2011).

1062. Plaintiffs are not suing because Bayer's and Conceptus' conduct violated federal law. Instead, Plaintiffs are suing based on the premise that Bayer's and Conceptus' conduct violates parallel regulations and requirements under Pennsylvania law.

1063. Pennsylvania law does not impose requirements that are different from, or in addition to requirements under federal law, and therefore Plaintiffs' claims are not preempted. Although Plaintiffs cannot bring a negligence *per se* claim based on violations of the FDA regulations and FDCA provisions, Pennsylvania courts have held that federal laws can support the existence of a duty of care in a negligence action.¹⁵⁰ In essence, Pennsylvania law incorporates FDA standards of care as a part of the duty of care in state law negligence actions; therefore, state law duties in this instance are identical to requirements of federal law, FDA Regulations, PMA requirements and the PMA Conditions of Approval.

1064. Conceptus and Bayer had a continuing duty under the various regulations discussed above and per the terms of the PMA approval by the FDA to monitor its product after receiving FDA approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences and other such serious events of which they became aware.

1065. Conceptus and Bayer failed to perform these duties under federal law to warn the FDA, and thus failed to perform its duty under Pennsylvania law, as these Defendants had a parallel duty to report and warn the FDA and other third parties of dangers associated with medical devices marketed for uses intended by them.

¹⁵⁰ *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Pa., Mar. 22, 2016) (citing *Phillips v. A.P. Green Refractories Co.*, 630 A.2d 874 (Pa. Super. 1993)); *Lance v. Wyeth*, 624 Pa. 231, 269-70, 85 A.3d 434, 456-57 (2014).

1066. Under the above Restatement, which has been adopted by Pennsylvania, the FDA is a “third person” in a position to reduce the foreseeable risks and harms suffered by Plaintiffs in their use of Essure®; thus, these Defendants had identical federal and state law duties to inform the FDA of the adverse events they knew or had reason to know about regarding Essure®, so consumers, such as Plaintiffs, and their physicians were properly informed of the dangerous conditions of the Essure® device and the facts which made it likely to be dangerous, so as to provide adequate warning of foreseeable risks of harm.

1067. Alternatively, Conceptus and Bayer had a duty to warn of foreseeable harms regarding the Essure® device by taking steps to modify the labeling to include harms, risks and benefits of the Essure® device that were not known or apparent at the time the FDA gave its PMA approval to the Essure® labeling, but which later became apparent through multiple reports of Adverse Events, which Bayer and Conceptus failed to timely report to the FDA and failed to adequately investigate. This state law duty to modify the labeling is identical to the federal duty under Essure®’s PMA “Conditions of Approval, “which required Bayer and Conceptus to “[s]ubmit a PMA supplement when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.” Had Bayer and Conceptus conformed to these duties, Plaintiffs and their physicians would have been adequately warned.¹⁵¹

1068. Bayer and Conceptus could have submitted a CBE under 21 C.F.R. § 803.39(d) to seek such a modification or could have submitted a PMA supplement so seeking. Bayer and Conceptus failed to do either and thus violated its federal and state law parallel duties to modify

¹⁵¹ *Maya v. Johnson and Johnson*, 97 A.3d 1203, 1213-14 (Pa. Super. 2014) (citing *Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009) and *Daniel v. Wyeth*, 15 A.3d 909 (Pa. Super. 2011)), *appeal granted in part*, 32 A.3d 1260 (Pa. 2011), *appeal dismissed as improvidently granted*, 82 A.3d 942 (Pa. 2013), *see also Cochran v. Wyeth, Inc.*, 3 A.3d 673, 676-77 (Pa. Super. 2010), *appeal denied* 20 A.3d 1209 (Pa. 2011).

the labeling and include the information to which it had access, through the adverse events (AEs) which it failed to report. Bayer's and Conceptus' state law duties to modify the labeling are simply additional reasons for them to perform their federal duties, explained above.

1069. Pennsylvania law exists independently of federal law. Here, Plaintiffs are not attempting to enforce federal law. Instead, Plaintiffs are seeking to hold Conceptus and Bayer liable for violating the state law duties to warn of the known dangers of Essure[®], which parallel federal regulations and requirements.

C. THERE IS A CAUSAL AND FACTUAL NEXUS BETWEEN PLAINTIFFS' INJURIES AND THE BAYER DEFENDANTS' BREACH OF THEIR STATE LAW DUTIES, AND IDENTICAL FEDERAL REQUIREMENTS.

1070. As discussed in detail above, Conceptus and Bayer failed to review, investigate, evaluate, record and report adverse events, and/or timely report adverse events, including but not limited to: complaints of device migration, device fracture/breakage, perforation, heavy menstrual cycle bleeding, autoimmune-like symptoms, allergic reactions, and long-term chronic pain, all of which are serious injuries or may lead to a serious injury because such injuries have, or may in the future, cause Plaintiffs to undergo surgical intervention to prevent further injury, and may cause long-term complications.¹⁵²

1071. As discussed in detail above, Conceptus and Bayer failed to report new clinical investigations and/or scientific studies concerning the Essure[®] device about which Conceptus and Bayer knew or reasonably should have known, including but not limited to the Cornell study, the article published in the online medical journal Conception, and the eight (8) articles describing 12 cases of Essure[®] abdominal migration published between January 2002 and December 2013 that were never reported to the FDA.¹⁵³

¹⁵² See 21 C.F.R. § 803.50; 21 C.F.R. § 814.80; and 21 U.S.C. § 360i(a).

¹⁵³ See 21 C.F.R. § 814.84(b)(2).

1072. As discussed in detail above, Conceptus and Bayer failed to: (1) analyze or identify existing potential causes of non-conforming products and other quality problems; (2) follow procedures used to control products which did not conform to specifications; (3) take any and all Corrective and Preventative Actions (“CAPA”) necessary to address non-conformance and other internal quality control issues; and/or (4) conduct adequate risk analysis.

1073. Had Conceptus and Bayer reported adverse events that it knew or had reason to know to the FDA, the FDA would have been in a position to reduce the risk of harm to the ultimate consumers of Essure® and would have moved to strengthen the warnings in the Essure® labeling much earlier than February 2016.

1074. Had Conceptus and Bayer analyzed and identified causes of non-conforming products and quality problems, conducted adequate risk analysis, and implemented CAPA as required, the FDA would have been on notice of harms of Essure® much earlier and would have been in a position to reduce the harm to consumers.¹⁵⁴ Instead, the non-compliance with quality control and CAPA is another example of the trend by Bayer and Conceptus to provide inadequate follow-up and reporting regarding adverse events associated with Essure®.

1. Had Bayer and Conceptus Reported Adverse Events Earlier, the FDA Would Have Moved to Strengthen the Essure® Labeling Much Earlier, Prior to Plaintiffs’ Implantations.

1075. As described above, the information that led the FDA to take steps to strengthen the labeling was available much earlier to these Defendants and this information would have led the FDA to strengthen the labeling much earlier, before implantation of the device into Plaintiffs. However, Bayer and Conceptus failed to report adverse events to the FDA and thus Plaintiffs and

¹⁵⁴ “Postmarket surveillance is designed to better identify uncommon but potentially serious adverse events related to the use of the device in the general public.” Analysis of Adverse Events With Essure Hysteroscopic Sterilization Reported to the Manufacturer and User Facility Device Experience Database, available at: [http://www.jmig.org/article/S1553-4650\(13\)00281-1/fulltext](http://www.jmig.org/article/S1553-4650(13)00281-1/fulltext) (last visited February 8, 2018).

their implanting physicians were not informed of the true risks and benefits of the Essure® device prior to Plaintiffs' surgeries.

1076. Had Bayer and Conceptus timely reported adverse events to the FDA that they either knew about or should have known, FDA would have provided a warning of foreseeable risks of harm to Plaintiffs' implanting physicians, who would have been in a position to inform Plaintiffs of these risks.

1077. Had Plaintiffs been informed of these risks, they would have declined to have the device implanted and they would not have suffered injuries.

2. Had Bayer and Conceptus Investigated and Reported Adverse Events Earlier, the Information in those AEs Would Have Been Available to the Medical Community as a Whole.

1078. Under state and federal law, Conceptus and Bayer are charged with knowing the risks and benefits of their medical device products. Nevertheless, these Defendants did not reveal their knowledge or investigate the causes of these adverse events. Instead, women implanted with the Essure® device reported adverse events directly to the FDA through the "MedWatcher app."¹⁵⁵

1079. As stated above, approximately 90% of all Essure® related adverse events were reported from October of 2013 to December of 2015 by patients through MedWatcher.

1080. The FDA publishes adverse events and MDRs in a public, searchable database called MAUDE and updates the report monthly with all reports received prior to the update. The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices. For example, in October of 2015, Dr. Dhruva, *et al.* published a study in the New England Journal of Medicine entitled *Revisiting Essure – Toward Safe*

¹⁵⁵ See "Increasing Patient Engagement in Pharmacovigilance Through Online Community Outreach and Mobile Reporting Applications: An Analysis of Adverse Event Reporting for the Essure Device in the US" available online at: <http://link.springer.com/article/10.1007/s40290-015-0106-6/fulltext.html>

and *Effective Sterilization*, which assessed the safety and effectiveness of Essure®.¹⁵⁶ This study was based in part on a search and analysis of the MAUDE database. The study concluded that the increase in reported Essure® related adverse event complaints since mid-2013 led the FDA to update Essure®'s patient label in 2014 to include information about risks of chronic pelvic pain and device migration into the lower abdomen and pelvis, and led to the FDA's decision to reconvene its Obstetrics and Gynecology Devices Panel to reassess Essure®'s safety and effectiveness on September 24, 2015.

1081. Similarly, a study published in November 2013 in *The Journal of Minimally Invasive Gynecology* entitled *Analysis of Adverse Events With Essure Hysteroscopic Sterilization Reported to the Manufacturer and User Facility Device Experience Database*, utilized the FDA's MAUDE database.¹⁵⁷ The study objectively stated that the MAUDE database is useful for clinicians using an FDA approved medical device to identify the occurrence of adverse events and complications.

1082. If Conceptus and Bayer had timely and accurately investigated such adverse events and reported them to the FDA, these reports would have been publicly available and would have effectively warned Plaintiffs' physicians both directly, such as through the MAUDE database, and through the discussion of adverse events that would have occurred in the published literature and in the medical community, much earlier.

1083. Because of Conceptus' and Bayer's failures, Plaintiffs' surgeons relied on inadequate, false and misleading information concerning the benefits and harms when deciding to use the Essure® device in Plaintiffs' surgeries.

¹⁵⁶ See "Revisiting Essure — Toward Safe and Effective Sterilization," available at: <http://www.nejm.org/doi/full/10.1056/NEJMp1510514> (last visited February 8, 2018).

¹⁵⁷ See "Analysis of Adverse Events With Essure Hysteroscopic Sterilization Reported to the Manufacturer and User Facility Device Experience Database," available at: [http://www.jmig.org/article/S1553-4650\(13\)00281-1/fulltext](http://www.jmig.org/article/S1553-4650(13)00281-1/fulltext) (last visited February 8, 2018).

3. Had Bayer and Conceptus Modified the Essure® Labeling as Required under State and Federal Law, Information Regarding the True Risks, Harms and Benefits of Essure® Would Have Been Available Much Earlier.

1084. Defendants were aware that the intended uses of Essure® were likely to cause adverse events that were neither as safe nor as effective as available alternative products and medical treatments. These harms, risks and benefits (revealed by adverse events reported to Bayer only after the original PMA approval of the labeling) were not contained in the original labeling and therefore were not adequately reported in that labeling.

1085. Bayer and Conceptus failed to comply with the Essure® PMA “Conditions of Approval,” and 21 C.F.R. § 814.39 which required them to “[s]ubmit a PMA supplement when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.”

1086. Bayer and Conceptus could have complied with its requirements under the Conditions of Approval (and/or the FDA Regulations) by either submitting a CBE under 21 C.F.R. §803.39(d), or by filing a supplemental PMA to modify the warnings to reflect the true harms, risks and benefits of the device.

1087. Had an appropriate warning regarding the risks associated with the use of Essure® been provided, Plaintiffs’ physicians would not have used the device and Plaintiffs would not have consented to its use.

4. Had Bayer and Conceptus Conformed to their Identical State and Federal Duties, Plaintiffs’ Specific Injuries Would Not Have Occurred.

1088. As a direct and proximate cause of one or more of the above-listed dangerous conditions, defects and negligence, Plaintiffs sustained serious injuries of a personal and pecuniary nature from the date of their Essure® surgeries to the present.

1089. Plaintiffs suffered from injuries including, but not limited to, pain subsequent surgeries, heavy bleeding, hair loss, rashes, dyspareunia, joint pain, autoimmune-like symptoms and allergic reactions following their Essure[®] implantations.

1090. Because Conceptus and Bayer failed to submit and/or timely submit a PMA supplement and make a labeling change to add or strengthen a contraindication, warning, precaution, or information about an adverse reaction, there is reasonable evidence of a causal association between Plaintiffs' injuries and these Defendants' failures to comply with federal and state duties; such evidence includes but is not limited to the thousands of reported and unreported adverse events consisting of serious injuries and pregnancies, the numerous Essure[®] studies consisting of thousands of women reporting that patients who undergo the Essure[®] procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and the over 30,000 unreported complaints contained in Conceptus' and Bayer's complaint files.

1091. The 2002 Essure[®] label described cramps as a typical temporary effect, and only described a micro-insert outside of the fallopian tube as an "incorrect position" found in the clinical studies, among three other issues including perforation, expulsion and placement too far or not far enough in the tube, in 4% of women at a routine 3-month follow up.¹⁵⁸

1092. It was not until October of 2013 that Conceptus changed the patient information booklet to include risks of chronic pain and device migration.¹⁵⁹ However, the modified label stated: "There are reports of the Essure[®] insert migrating." This modification of the labeling provided only a vague reference, and would have been much stronger and more informative, as

¹⁵⁸ Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014D.pdf (last accessed February 8, 2018).

¹⁵⁹ Available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014S040> (last visited February 8, 2018).

required by the FDA in 2016, had the true information regarding adverse events been reported and investigated by these Defendants.

1093. Had Bayer and Conceptus complied with the PMA and timely reported adverse events, applied for a PMA supplement, or unilaterally changed the label through a CBE, Plaintiffs and their physicians would have been warned of the true adverse events and incidence of adverse events prior to Plaintiffs' surgeries, and would not have elected to use Essure® for Plaintiffs' permanent sterilization needs.

1094. Defendants' conduct, as alleged above, was malicious, oppressive, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs and warrants an award of punitive damages.

D. CONCEPTUS AND BAYER FAILED TO ACCURATELY REPORT ADVERSE EVENTS FROM THE CLINICAL TRIALS.

1095. Conceptus and Bayer had federal duties to accurately report all adverse events, including those from their clinical trials.¹⁶⁰

1096. Conceptus and Bayer breached their federal duties to report adverse events from the clinical trials.

1097. As discussed above, Defendants had parallel duties under Pennsylvania law to adequately warn Plaintiffs and their physicians of the true incidence of adverse events. Pennsylvania state law is concerned with the protection of consumers from harm caused by a manufacturer's unreasonable behavior, and imposes upon these manufacturers a general duty of reasonable care.

1098. As discussed in *Stengel*, the standard for negligence imposes a duty on

¹⁶⁰ 21 U.S.C.S. § 360(e); 21 C.F.R. § 803.50(a).

manufacturers, like Defendants, to produce products with appropriate warning instructions. *Stengel* at 1233. Here, like in *Stengel*, Defendants failed to warn the FDA of adverse events, and such a warning is contemplated under parallel state law to a third party, such as the FDA.

1099. Plaintiffs' claim that Defendants failed to accurately report adverse events from their clinical trials is not a state-law fraud-on-the-FDA claim, and does not increase the burden of applicants for FDA approval of medical devices.¹⁶¹

1100. Here, Defendants had a state-law duty that is independent of the FDA's pre-market approval process, and does not exist solely by virtue of federal law. This state-law duty to warn is not different from, or in addition to, federal requirements under the MDA.

1101. Clinical trials provide data upon which physicians make professional judgments about the risks and benefits of a device, and whether it is proper to prescribe to their patients.

1102. Because of Defendants' failure to accurately report adverse events from their clinical trials, Plaintiffs and their physicians were not able to make an informed decision based on true representative data showing the safety and efficacy of the device.

1103. Had Bayer and Conceptus accurately reported data from the clinical trials, Plaintiffs and their physicians would have been warned of the true adverse events and incidence of adverse events prior to Plaintiffs' surgeries, and would not have elected to use Essure® for Plaintiffs' permanent sterilization needs.

E. TO THE EXTENT THE ESSURE® WARNING WAS ADEQUATE, IT WAS NULLIFIED BY DEFENDANTS' CONDUCT.

1104. The Essure® warning was nullified due to the reckless or intentional minimizing and/or downplaying of the risks of serious side effects, the misrepresentations, concealments and omissions, and/or the failure to report known adverse events by Conceptus and Bayer as described

¹⁶¹ *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343, 121 S. Ct. 1012, 1015 (2001).

generally above.

1105. Conceptus and Bayer created and distributed false and misleading advertising, including but not limited to representations and warranties regarding the risks, safety, recovery time, and effectiveness of Essure[®] in order to convince physicians and patients to use Essure[®] over other methods of permanent birth control, thereby gaining market share, in violation of 21 U.S.C. §§ 360(q); 360(r) and Pennsylvania law.

1106. Conceptus' and Bayer's misrepresentations and false and misleading promotion of Essure[®] nullified otherwise adequate warnings under Pennsylvania law.¹⁶²

F. ESSURE[®] IS AN "ADULTERATED" AND "MISBRANDED" DEVICE AND IS THEREFORE EXTRA-REGULATORY.

1107. A Class III device that fails to meet the PMA requirements after marketing is considered to be adulterated under § 351(f) of the Federal Food, Drug and Cosmetic Act ("FDCA").

1108. Under 21 U.S.C. § 352 and 35 P.S. § 780-108, a device is "misbranded" if its labeling is false or misleading in any particular.¹⁶³

1109. As detailed above, the Essure[®] device was manufactured, labeled, distributed, and/or advertised in a manner that is inconsistent with the Conditions for Approval specified in the PMA.¹⁶⁴

¹⁶² *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Pa., Mar. 22, 2016) (citing *Baldino v. Castagna, M.D.*, 505 Pa. 239, 478 A.2d 807, 810 (Pa. 1984) (citing *Incollingo v. Ewing*, 282 A.2d 206 (Pa. 1971)); *Wolfe v. McNeil-PPC, Inc.*, 773 F. Supp. 2d 561, 570-71 (E.D. Pa. 2011) (stating that "[a] plaintiff can bring a claim that the manner in which a drug is promoted negated otherwise-adequate warnings") (citing *Baldino*, 478 A.2d at 810)).

¹⁶³ See also 1 Pa.C.S. § 1929 (allowing for recovery of damages for violation of a Pennsylvania statute, and recovery against joint defendant) and 42 Pa.C.S. § 7102 (contribution).

¹⁶⁴ 21 C.F.R. § 814.80.

1110. Specifically, these Defendants failed to submit a PMA supplement for unanticipated adverse effects and increases in the incidence of anticipated adverse effects or device failures.¹⁶⁵

1111. As detailed above, Conceptus and Bayer concealed reports of adverse events, in violation of federal law, the PMA, and parallel state law.

1112. Further, Conceptus and Bayer (1) failed to appropriately respond to adverse incident reports, including but not limited to, reports of device migration outside of the fallopian tubes and/or device fracture/breakage, which strongly indicated the Essure[®] device was malfunctioning or otherwise not responding to its Design Objective Intent, which was to remain permanently in Plaintiffs' fallopian tubes, and (2) continued to place Essure[®] into the stream of interstate commerce when they knew, or should have known, that the Essure[®] was malfunctioning or otherwise not responding to its Design Objective Intent.

1113. Accurate and timely reporting of adverse events helps to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

1114. Bayer and Conceptus failed to comply with the PMA, thus making the Essure[®] device "adulterated" and extra-regulatory.

1115. Conceptus and Bayer promoted for sale misbranded and adulterated products because the Essure[®] label is false and misleading as Essure[®] is not a safer and more effective method of permanent sterilization than alternative methods, as evidenced by the over 10,000 reported adverse events consisting of serious injuries and pregnancies, by the numerous Essure[®] studies consisting of thousands of women reporting that patients who undergo the Essure[®] procedure are more likely to experience injuries and complications which require or will require

¹⁶⁵ See http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014a.pdf

surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus' and Bayer's complaint files.

1116. Plaintiffs are not suing to enforce federal law based on the adulterated status of the Essure[®] device, but are instead suing on the parallel state claims detailed above, which allow a state cause of action for damages due to Bayer's and Conceptus' failure to warn the FDA, Plaintiffs, and Plaintiffs' physicians of the misbranded condition of the device.

1117. Had Plaintiffs and their physicians known that Essure[®] was adulterated due to Conceptus' and Bayer's failure to comply with the PMA, Plaintiffs would not have chosen to have Essure[®] implanted in their fallopian tubes.

1118. Plaintiffs suffered from adverse events known to Bayer and Conceptus well before Plaintiffs' implant surgeries. Bayer and Conceptus chose to conceal adverse events in violation of the PMA, rendering Essure[®] adulterated.

1119. Therefore, Plaintiffs' injuries are causally and factually related to the adulterated status of Essure[®] due to Bayer's and Conceptus' failure to report adverse events in violation of the PMA.

WHEREFORE, Plaintiffs respectfully demand judgment in an amount in excess of the Arbitration limits in Allegheny County against all Bayer Defendants, and each of them, individually, jointly and severally, and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

- A) compensatory damages for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;
- B) for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;
- C) for specific damages according to proof;

- D) for Punitive and Exemplary damages according to proof;
- E) for pre-judgment interest and post-judgment interest as allowed by law;
- F) for reasonable attorneys' fees;
- G) for the costs of these proceedings; and
- H) for such other and further relief as this Court deems just and proper.

A JURY TRIAL IS DEMANDED.

SECOND CAUSE OF ACTION
Fraudulent Misrepresentation / Fraud in the Inducement
Restat. 2d of Torts § 525.

1120. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

1121. Plaintiffs brings a claim against Conceptus and Bayer under Pennsylvania law for fraudulent misrepresentation / fraud in the inducement regarding the Essure® device.

A. CONCEPTUS AND BAYER HAD AFFIRMATIVE AND CONTINUING FEDERAL DUTIES TO NOT MAKE FRAUDULENT MISREPRESENTATIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE®.

1122. The Essure® device that was implanted in Plaintiffs was promoted, distributed, manufactured and used in a manner that is in violation of federal law, the FDCA, the MDA, and regulations promulgated thereunder.

1123. Under the FDCA and FDA's implementing regulations, labeling and promotional advertisements, claims about medical devices are deemed misleading if they fail to disclose certain information about the product's risks.

1124. It was the duty of Conceptus and Bayer to comply with federal law, the FDCA, the MDA and the regulations. Notwithstanding this duty, Conceptus and Bayer violated federal law, the FDCA, the MDA, and the regulations, including but not limited to, in one or more of the

following ways:

- A) Conceptus and Bayer had duties to not make false or misleading statements regarding Essure[®] under 21 U.S.C. §§ 331(a), 351 & 352(a), (q) & (r); 21 U.S.C. §§ 360(q)&(r); and 21 C.F.R. § 814.80.
- B) Conceptus and Bayer had duties to investigate and address adverse events under the following regulations: 21 C.F.R. § 820.3(z)(x), 21 C.F.R. § 820.22, 21 C.F.R. § 820.5, 21 C.F.R. § 820.1(a), 21 C.F.R. § 820.22, 21 C.F.R. § 820.100; 21 C.F.R. § 820.160(a), 21 C.F.R. § 820.198; 21 C.F.R. § 820.30; 21 C.F.R. § 803.3; 21 C.F.R. § 820.70 and 21 C.F.R. § 820.170(a).
- C) Conceptus and Bayer had duties to submit a PMA supplement and make a labeling change to add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association under 21 C.F.R. § 814.39, 21 C.F.R. § 803.56.
- D) Conceptus and Bayer had duties to report adverse events under 21 C.F.R. § 803.50; 21 C.F.R. § 814.80, and 21 U.S.C. § 360i(a).
- E) Conceptus and Bayer had duties to report new clinical investigations and/or scientific studies concerning the Essure[®] device about which Conceptus and Bayer knew or reasonably should have known about under 21 C.F.R. § 814.84(b)(2).

1125. The above regulations imposed duties on Conceptus and Bayer to accurately, timely, and honestly represent to the FDA, the public, Plaintiffs and Plaintiffs' physicians, the safety and effectiveness of Essure[®].

B. CONCEPTUS AND BAYER HAD STATE DUTIES TO NOT MAKE FRAUDULENT MISREPRESENTATIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE[®].

1126. In Pennsylvania, a party claiming harm resulting from fraudulent misrepresentation/ fraud in the inducement must establish six elements of fraud by clear and convincing evidence as follows: a) a representation; b) which is material to the transaction at hand; c) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; d) with the intent of misleading another into relying on it; e) justifiable reliance on the

misrepresentation; and f) the resulting injury was proximately caused by the reliance.¹⁶⁶

1127. Further, Restatement 2d of Torts § 525 provides,

[o]ne who fraudulently makes a misrepresentation of fact, opinion, intention or law for the purpose of inducing another to act or to refrain from action in reliance upon it, is subject to liability to the other in deceit for pecuniary loss caused to him by his justifiable reliance upon the misrepresentation.¹⁶⁷

C. CONCEPTUS' AND BAYER'S DUTY TO NOT MAKE FRAUDULENT MISREPRESENTATIONS UNDER PENNSYLVANIA LAW IS NOT DIFFERENT FROM OR IN ADDITION TO FEDERAL REQUIREMENTS.

1128. Under both Pennsylvania state and federal law, Conceptus and Bayer were under parallel duties not to make fraudulent misrepresentations of material facts regarding the benefits and harms of the medical devices sold by them. The state law and federal duties are identical because both prohibit these Defendants from making misrepresentations in the sale of their medical devices;¹⁶⁸ thus, the state law cause of action alleged herein is just one more reason for these Defendants to conform to their duties under the FDCA, the MDA, the Essure[®] PMA, and FDA Regulations.

1129. Conceptus and Bayer were required to comply with the duties listed in Section B. above, and were required to be truthful, accurate, and timely in performing the duties under federal law, as detailed above.

¹⁶⁶ See *Gibbs v. Ernst*, 647 A.2d 882 (Pa. 1994) (citing Restatement (Second) of Torts § 525 (1977)).

¹⁶⁷ See *Marra v. Burgdorf Realtors, Inc.*, 726 F. Supp. 1000 (E.D. Pa. 1989) (citing Restatement (Second) of Torts § 525).

¹⁶⁸ See, e.g., 21 U.S.C. § 352(q) and 21 U.S.C. § 321(n), 35 P.S. § 780-108 Misbranding. See also, *United States v. Shabbir*, 64 F. Supp. 2d 479, 481 (D. Md. 1999), which explains: The FDCA regulates, *inter alia*, the introduction of certain articles into the United States. See 21 U.S.C. § 301 et seq. Section 331 prohibits "the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated and misbranded." 21 U.S.C. § 331(a). n1 "[A] drug or device shall be deemed to be misbranded (a) if its labeling is false or misleading in any particular. . . ." 21 U.S.C. § 352. "Labeling" is expansively defined, and includes "all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321 (m).

1130. Pennsylvania law does not impose requirements that are different from, or in addition to requirements under federal law, and therefore Plaintiffs' claims are not preempted.

1131. Pennsylvania law exists independently of federal law. Here, Plaintiffs are not attempting to enforce federal law. Instead, Plaintiffs are seeking to hold Conceptus and Bayer liable for violating the state law duties to not make false and misleading statements regarding Essure®, which parallel federal regulations and requirements.

D. THERE IS A CAUSAL AND FACTUAL NEXUS BETWEEN PLAINTIFFS' INJURIES AND DEFENDANTS' BREACH OF ITS STATE LAW DUTIES, AND IDENTICAL FEDERAL REQUIREMENTS.

1132. Conceptus and Bayer breached their duties under federal and state laws, as follows:

- A) Fraudulently misrepresented the health and safety hazards, symptoms, diseases and/or health problems associated with use of Essure® for the purposes intended by these Defendants;
- B) Fraudulently misrepresented their illegal, improper and unethical schemes to promote and market Essure® as "simple" and "worry-free"; and
- C) Fraudulently misrepresented information about the known comparative risks and benefits of the use of Essure® and the relative benefits and availability of alternate products, treatments and/or therapies.

1133. As described above in this Complaint, to promote the perceived safety of the device and gain market acceptance, Conceptus devised and implemented a scheme to defraud physicians and patients, by means of false and fraudulent pretenses, so physicians and their patients would believe Essure® to be a safe and effective product, and thus increase the demand and profitability.

1. Conceptus and Bayer Intentionally Misrepresented the Health and Safety Information Associated with Essure®.

1134. In connection with the Essure® product, Conceptus and Bayer fraudulently and intentionally misrepresented material and important health and safety product risk information to Plaintiffs and Plaintiffs' physicians, all as alleged in this Complaint.

1135. For example, Conceptus and Bayer used the Essure[®] label to increase revenue,¹⁶⁹ and in doing so made false and misleading statements about the safety and efficacy of Essure[®] to Plaintiffs and Plaintiffs' physicians, as it concealed important health and safety information from the FDA and failed to follow proper quality control measures, regulations, and/or implement CAPAs; thus, rendering the label false.

1136. The Essure[®] label at the time of Plaintiffs' implants represented that Essure[®] was a safer and more effective method of permanent sterilization than alternative methods. This is false and misleading, as evidenced by the over 10,000 reported adverse events consisting of serious injuries and pregnancies, by the Essure[®] studies consisting of thousands of women and reporting that patients who undergo the Essure[®] procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, as well as by the over 30,000 unreported complaints contained in Conceptus and Bayer's complaint files.

1137. Bayer and Conceptus presented false and misleading information after being caught by the FDA in 2011 for not reporting migration events. It was not until October of 2013 that Conceptus changed the warning label to state only that "There are reports of the Essure insert migrating." This warning gravely downplayed the true incidence of risk that a woman's Essure[®] coils might migrate.

1138. Conceptus and Bayer represented to the FDA, the public, Plaintiffs and Plaintiffs' implanting physicians that Essure[®] was less invasive and less costly than tubal ligation, required no incision or general anesthesia, no abdominal entry for implantation, and could be implanted in an office setting. These Defendants also represented that Essure[®] was beneficial to patients

¹⁶⁹ In 2008, Conceptus stated for the 2007 fiscal year that it intended to make labeling improvements to Essure[®] to increase the adoption of the Essure[®] procedure. *See* [http://www.wikininvest.com/stock/Conceptus_\(CPTS\)/Filing/10-K/2008/F2331313](http://www.wikininvest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313)

because there were no risks associated with hormones, which are used in hormone-based contraception, and no recurring management of contraception.¹⁷⁰

1139. These representations were false and misleading and were intentionally and fraudulently made to generate sales.

1140. Conceptus stated that they were a “one product company and if our product fails to gain market acceptance, our business will suffer... [w]e are dependent on the Essure® system.”¹⁷¹

1141. Conceptus believed that the recommendations and endorsements of physicians would be essential for market acceptance of Essure®, and that physicians would not endorse the product unless it was an attractive alternative to other forms of contraception and more cost-effective.¹⁷²

1142. Evidence that these representations were intentionally false and misleading can be seen in the adverse event reporting that occurred subsequent to the launch of the MedWatcher app.

1143. A retrospective study published in November 2013 in *The Journal of Minimally Invasive Gynecology* entitled *Analysis of Adverse Events With Essure Hysteroscopic Sterilization Reported to the Manufacturer and User Facility Device Experience Database*,¹⁷³ analyzed and investigated reports associated with the Essure® hysteroscopic sterilization system from November of 2002 to February of 2012 using the MAUDE database. The study found that 457 adverse events were reported during this period, which included 217 reports of pain, 121 events of delivery catheter malfunction, 61 reports of post-sterilization pregnancy, of which 29 were ectopic

¹⁷⁰ See “Revisiting Essure — Toward Safe and Effective Sterilization,” available at:

<http://www.nejm.org/doi/pdf/10.1056/NEJMp1510514>; and *see*

[http://www.wikinest.com/stock/Conceptus_\(CPTS\)/Filing/10-K/2008/F2331313](http://www.wikinest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313)

¹⁷¹ See [http://www.wikinest.com/stock/Conceptus_\(CPTS\)/Filing/10-K/2008/F2331313](http://www.wikinest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313)

¹⁷² See [http://www.wikinest.com/stock/Conceptus_\(CPTS\)/Filing/10-K/2008/F2331313](http://www.wikinest.com/stock/Conceptus_(CPTS)/Filing/10-K/2008/F2331313)

¹⁷³ See “Analysis of Adverse Events With Essure Hysteroscopic Sterilization Reported to the Manufacturer and User Facility Device Experience Database,” available at: [http://www.jmig.org/article/S1553-4650\(13\)00281-1/fulltext](http://www.jmig.org/article/S1553-4650(13)00281-1/fulltext) (last visited January 31, 2018).

pregnancies, 90 events of perforation, 44 reports of abnormal bleeding and 33 events of microinsert malposition. There were 270 cases (which is 59.1% of all reported adverse events) where the adverse events resulted in an additional surgical procedure, of which 44 were hysterectomies.

1144. Another study, *Increasing Patient Engagement in Pharmacovigilance Through Online Community Outreach and Mobile Reporting Applications: An Analysis of Adverse Event Reporting for the Essure® Device in the US*,¹⁷⁴ examined voluntary patient adverse event reporting directly to the FDA using the FDA's new MedWatcher app. The study began by encouraging women in an Essure® support group who had been adversely affected by the device to file a report using MedWatcher.

1145. The study analyzed data collected from May 11, 2013 to December 7, 2014, which included 1349 women who reported adverse events through MedWatcher. The study found that 1047 women (77.6%) reported serious events such as hospitalization, disability and permanent damage after implantation.

1146. When the MedWatcher app launched in the fall of 2013, and women started to report adverse events from Essure® directly to the FDA, Bayer chose to continue promoting the device as safe.

1147. Between May 29, 2014 and January 20, 2016, Bayer received 462 complaints that a patient's Essure® coils had broken apart. Bayer submitted the reports of breakage in an intentionally misleading manner. When forwarding the first few complaints, Bayer notified the FDA that "single cases have been reported of Essure breakage." However, as reports of breakage continued to mount, Bayer continued to submit to the FDA that only single cases of breakage

¹⁷⁴ See "Increasing Patient Engagement in Pharmacovigilance Through Online Community Outreach and Mobile Reporting Applications: An Analysis of Adverse Event Reporting for the Essure Device in the US" available online at: <http://link.springer.com/article/10.1007/s40290-015-0106-6/fulltext.html> (last visited January 31, 2018).

had been reported. Bayer's MDRs regarding device breakage were inaccurate, misleading, and not in compliance with MDR reporting requirements.

1148. On October 8, 2015, Dr. Dhruva, *et al.* published a study in the New England Journal of Medicine entitled *Revisiting Essure – Toward Safe and Effective Sterilization*, which assessed the safety and effectiveness of Essure®. This study was based in part on a search and analysis of the MAUDE database. The study concluded that the increase in reported Essure® related adverse event complaints since mid-2013 led the FDA to update Essure®'s patient label in 2014 to include information about risks of chronic pelvic pain and device migration into the lower abdomen and pelvis and led to the FDA's decision to reconvene its Obstetrics and Gynecology Devices Panel to reassess Essure®'s safety and effectiveness on September 24, 2015.

1149. The number of patient-reported adverse events following the launch of the MedWatcher app evidence a strong contradiction to the safety and efficacy of Essure® as reported by Conceptus and Bayer.

1150. As thousands of reports about Essure®'s true safety risks became public recently, the FDA mandated changes to the product's warning label and took measures to ensure that patients are fully informed of the risks by requiring patients to fill out the "Patient Decision Checklist."

1151. As medical device manufacturers, Conceptus and Bayer had a duty to not present false and misleading information about the Essure® device to the public, including Plaintiffs and Plaintiffs' physicians regarding the increased risks and dangers they knew, learned, or should have known about associated with Essure®.

1152. Had Conceptus and Bayer complied with their duties to the FDA as described under the FDCA and detailed above in this Complaint, the necessary and resultant actions by the FDA

and/or appropriate government agencies would have precluded the use of the product by Plaintiffs and Plaintiffs' physicians.

2. Conceptus and Bayer Made Intentional Misrepresentations Regarding the Safety and Efficacy of Essure® Through Marketing.

1153. Conceptus conducted enormous and aggressive marketing campaigns that disseminated what they knew to be false and misleading statements pertaining to the convenience, safety and efficacy of the device.

1154. Conceptus and Bayer created and distributed false and misleading advertising for Essure®, which is a "Restricted Device," because Essure® is not a safer and more effective method of permanent sterilization than alternative methods, evidenced by the over 10,000 reported adverse events consisting of serious injuries and pregnancies, by the Essure® studies consisting of thousands of women reporting that patients who undergo the Essure® procedure are more likely to experience injuries and complications which require or will require surgical intervention or re-operation, and by the over 30,000 unreported complaints contained in Conceptus' and Bayer's complaint files.

1155. For example, the Essure® website, print advertising, and patient brochure stated, "the Essure® inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place." However, the micro-inserts can migrate, as evidenced by the over 1,485 reports of device migration as of December 31, 2016,¹⁷⁵ which would have deterred Plaintiffs and their physicians from using Essure® in Plaintiffs.

¹⁷⁵ See

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm> (last visited January 31, 2018).

1156. As a further example, the Essure[®] website, print advertising, and patient brochure stated, “Essure[®] eliminates the risks, discomfort, and recovery time associated with surgical procedures.” This is false and misleading, as many women, including Plaintiffs, have experienced lifelong complications from the device and have required surgical removal of the device, which typically requires removal of organs such as the fallopian tubes and uterus. All three Plaintiffs unfortunately required subsequent surgeries as a result of adverse events regarding their Essure[®] devices. Further, the British Medical Journal (“BMJ”) published a study entitled *Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study*,¹⁷⁶ in which Dr. Art Sedrakyan of Weill Cornell Medicine in New York and his colleagues analyzed data from women who had received either the Essure[®] implant or had undergone a traditional tubal ligation between 2005 and 2013 in New York State. The study found that women who used Essure[®] as a means for permanent sterilization are ten times more likely to undergo re-operation within one year of the initial procedure due to device related complications and injuries compared to women who undergo tubal ligation. Further, “[g]eneral anesthesia was less frequently used when performing hysteroscopic sterilization compared with laparoscopic sterilization but it was still used in about half of the patients. This finding is remarkable in light of the marketing and proposed benefits of avoiding general anesthesia associated with the Essure[®] device.”

1157. The Essure[®] patient brochure stated that Essure[®] was the “only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials.” However, there were actually four pregnancies during the clinical trials and five pregnancies during the first year of commercial experience. Between 1997 and 2005, there were 64 pregnancies reported to

¹⁷⁶ See “Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study” available online at: <http://www.bmj.com/content/351/bmj.h5162>

Defendants. Additionally, there have been 1,113 reports of pregnancies according to the FDA as of December 31, 2016. Furthermore, a recent study indicates that women implanted with Essure® have a *ten times* greater risk of pregnancy after one year than those who use laparoscopic sterilization.

1158. The Essure® website, print advertising, and patient brochure describes Essure® as “worry free,” and as a “simple procedure performed in your doctor’s office” that takes “less than 10 minutes” and “requires no downtime for recovery” and “Essure® eliminates the risks, discomfort, and recovery time associated with surgical procedures.” However, Essure® is not worry free because there is an increased risk that the Essure® implants will cause women serious, life-altering complications including but not limited to debilitating pain, heavy bleeding necessitating medication and/or additional surgical intervention, allergic reactions, autoimmune-like symptoms, dyspareunia, hysterectomy, and other complications.

1159. The Essure® website, print advertising, and patient brochure stated, “the Essure® inserts are made from the same trusted, silicone free material used in heart stents.” However, the micro-inserts are not made from the same material as heart stents. In contrast, the micro-inserts in Essure® are made of PET fibers, which trigger inflammation and scar tissue growth. PET fibers degrade and leach carcinogens when placed in temperatures over 65 degrees, and the human body stays at about 98 degrees. As such, PET fibers are not designed or manufactured for use in human implantation. However, the PET fibers are made of the same materials as the PVT material in some vaginal meshes, which have a high rate of expulsion.

1160. The Essure® website, print advertising, and patient brochure stated, “Essure® eliminates the risks, discomfort, and recovery time associated with surgical procedures.” However, Essure® does not eliminate the risks, discomfort, and recovery time associated with surgical procedures (i.e. tubal ligations) because many women who undergo the Essure®

procedure, including Plaintiffs, have never and will never fully recover from the Essure[®] implant procedure, which has caused them serious complications, including but not limited to debilitating pain, additional surgical procedures, allergic reactions, autoimmune-like symptoms, and other complications.

1161. The Essure[®] website, print advertising, and patient brochure stated, “Essure[®] is the most effective permanent birth control available, even more effective than tying your tubes or a vasectomy” or words to that effect. Yet, Defendants’ SEC Form 10-K filing shows that Defendants never did a comparison to a vasectomy or tubal ligation. Specifically, Defendants stated they “did not conduct a clinical trial to compare the Essure[®] procedure to laparoscopic tubal ligation.”¹⁷⁷

1162. The Essure[®] website claimed, “correct placement...is performed easily because of the design of the micro-insert.” However, Defendants admitted that placement of the device requires a “skilled approach” and admitted that even their own experts in hysteroscopy failed to place the micro-inserts in one out of seven clinical participants.

1163. Conceptus and Bayer advertised, promoted and marketed on its websites, in its print and/or video advertisements, brochures, and fact sheets the following about physicians performing the Essure[®] procedure:

- A) “[p]hysicians must be signed-off to perform Essure procedure.” However, Defendants failed to adequately train the implanting physician and “signed off” on the implanting physician who did not have the requisite training.
- B) “An Essure[®] trained doctor inserts spring-like coils, called micro-inserts.” However, the implanting physician who implanted the device was not adequately trained.
- C) “The Essure[®] training program is a comprehensive course designed to provide information and skills necessary to select appropriate patients,

¹⁷⁷ Conceptus, Inc., Annual Report (Form 10-k) (Mar. 15, 2004).

perform competent procedures and manage technical issues related to the placement of Essure® micro-inserts for permanent birth control.” However, Defendants failed to adequately train the implanting physician.

- D) “[i]n order to be trained in Essure® you must be a skilled operative hysteroscopist. You will find the procedure easier to learn if you are already proficient in operative hysteroscopy and management of the awake patient. If your skills are minimal or out of date, you should attend a hysteroscopy course before learning Essure®.” However, Defendants “signed off” on physicians who were not skilled operative hysteroscopists, in order to monopolize and capture the market, including the implanting physician.
- E) “[i]n order to be identified as a qualified Essure® physician, a minimum of one Essure® procedure must be performed every 6–8 weeks”. However, Defendants “signed off” on “Essure® physicians” who did not perform the procedure every 6–8 weeks.
- F) “[t]he PET fibers are what caused the tissue growth,” and Essure® “works with your body to create a natural barrier against pregnancy.” However, during a PMA meeting with the FDA in 2002, Defendants represented that the trauma caused by the expanding coil hitting the fallopian tubes is what causes the inflammatory response of the tissue.

3. Conceptus and Bayer Intentionally Misrepresented the Comparative Risks and Benefits of Essure® to Alternative Methods of Permanent Sterilization.

1164. Conceptus engaged in substantial, widespread and systemic false, misleading and illegal promotional activities to encourage physicians and patients to use the Essure® device.

1165. Conceptus represented that Essure® had the following “key advantages” over laparoscopic tubal ligation: transcervical placement (non-incisional, compared to an abdominal incision or puncture), local, IV sedation (compared to general anesthesia), 45 minutes of average post-op recovery (compared to 4-5 hours of average post-op recovery), procedure performance in an outpatient/hospital, surgical center or doctor’s office (compared to procedure performance in an inpatient/hospital or surgical center), and a 1-2 day average wait time to return to regular activities (compared to 4-6 days).

1166. However, the BMJ study, *Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study*,¹⁷⁸ found that women who used Essure® as a means for permanent sterilization are ten (10) times more likely to undergo re-operation within one (1) year of the initial procedure due to device related complications and injuries compared to women who undergo tubal ligation. “A more than 10-fold higher occurrence of reoperation during the first year following Essure® based surgery is a serious safety concern.” As indicated in this study, “additional surgeries were performed to alleviate complications such as device migration or incompatibility after surgery.”

1167. The BMJ article also reported “[t]he hysteroscopic procedure with Essure® device does not require general anesthesia, and its safety has been considered to be similar or superior to that of laparoscopic sterilization.” However, this study found that “[g]eneral anesthesia was less frequently used when performing hysteroscopic sterilization compared with laparoscopic sterilization but it was still used in about half of the patients.”

1168. Additionally, the authors analyzed the Essure® MAUDE data and indicated that most of the adverse events reported by patients with Essure® were for injuries that would require and did require a subsequent surgical operation. Such injuries included pelvic pain, hemorrhage, and device migration or incompatibility.

1169. Conceptus and Bayer did not submit any MDR reportable events derived from this study and reported in the BMJ to the FDA.

1170. In March of 2014, the online medical journal Conception published a study entitled *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic*

¹⁷⁸ See “Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study” available online at: <http://www.bmj.com/content/351/bmj.h5162> (last visited January 31, 2018).

sterilization, which compared the expected probability of pregnancy after hysteroscopic sterilization with laparoscopic sterilization based on available data using decision analysis.¹⁷⁹ The authors concluded that at all points in time after the sterilization procedure, the initial and cumulative risk of pregnancy after sterilization is higher in women who undergo hysteroscopic sterilization than either laparoscopic band or bipolar sterilization.

1171. Bayer still falsely claims that Essure® is more effective than undergoing tubal ligation.

4. As a Direct, Proximate and Causal Result of Conceptus' and Bayer's Fraudulent Misrepresentations, Plaintiffs Sustained Substantial Injuries.

1172. Conceptus engaged in the above activities despite knowing that manipulating the public's knowledge of safety risks associated with Essure® exposed patients to serious dangers and greatly increased adverse risks.

1173. Conceptus and Bayer intentionally and consciously misrepresented the benefits and harms associated with Essure®.

1174. These Defendants knew that doctors such as Plaintiffs' implanting physicians would rely on such misrepresentations, thus subjecting their patients, like Plaintiffs, to an unreasonable risk of physical harm. Such misrepresentations corrupted resources available to surgeons, like Plaintiffs' implanting surgeons, regarding the safety and effectiveness of Essure®.

1175. Conceptus' and Bayer's motive in failing to advise surgeons, the public, Plaintiffs, and the FDA of these increased risks was for financial gain and fear that, if they provided proper and adequate information, Essure® would lose sales and market share.

¹⁷⁹ See "Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization" available at: <http://www.contraceptionjournal.org/pb/assets/raw/Health%20Advance/journals/contr/CON-8309-FINAL.pdf> (last visited January 31, 2018).

1176. Conceptus and Bayer chose not to provide the Plaintiffs' physicians nor Plaintiffs with the necessary information in order to make an informed decision in the best interests of Plaintiffs' health, and they purposefully deceived Plaintiffs' physicians and the Plaintiffs as to the safety and efficacy of Essure®.

1177. Conceptus and Bayer provided inaccurate, false, or misleading information which was material to Plaintiffs' implanting physicians' treatment decisions, which misled Plaintiffs' physicians and Plaintiffs who were relying on their physicians' professional judgment.

1178. Conceptus and Bayer knew that use of Essure® was unreasonably dangerous and could lead to serious side effects as listed herein. Conceptus and Bayer failed to take any measures whatsoever to alert surgeons or the public regarding increased risks and dangers and instead continued to promote the Essure® device as safe.

1179. When Conceptus and Bayer engaged in this deceptive campaign and made the above representations, they knew those representations to be false. These representations were made by Conceptus and Bayer with the intent of defrauding and deceiving the public, including Plaintiffs, Plaintiffs' physicians, and the medical community.

1180. At the time the aforesaid representations were made by Conceptus and Bayer, Plaintiffs and their medical providers were unaware of the falsity of said representations and reasonably relied upon Conceptus' and Bayer's assertions, promulgated through aggressive sales tactics as set forth herein, that the Essure® device was safe when in fact it was not.

1181. As detailed above, Bayer continues false claims that Essure® is safer and more effective than undergoing tubal ligation.

1182. Conceptus and Bayer intended to induce Plaintiffs and their physicians to rely on their misrepresentations to use Essure® over the alternative methods of permanent sterilization.

1183. In reliance upon Conceptus and Bayer's representations, Plaintiffs and Plaintiffs' physicians used Essure®.

1184. Plaintiffs and Plaintiffs' physicians were justified in their reliance on Conceptus' and Bayer's representations and marketing. Plaintiffs actually did undergo the Essure® implant procedure, which ultimately caused Plaintiffs' serious physical injuries.

1185. As a direct and proximate result of said misrepresentations, Plaintiffs have been injured and have incurred damages, including but not limited to medical and hospital expenses, lost wages and lost earning capacity, physical and mental pain and suffering, and loss of the enjoyment of life.

1186. Had Plaintiffs' implanting physicians and Plaintiffs been made fully and adequately aware of the inefficacy and serious increased risks and dangers associated with such use, Plaintiffs' physicians would not have recommended Essure® to Plaintiffs and Plaintiffs would not have chosen to have Essure® implanted in their fallopian tubes.

1187. Had the FDA known of the actual dangers of and inefficacy of the use of Essure®, they would have initiated a recall of the product, dear doctor letter, or safety signal and/or warned the public of the danger.

1188. Conceptus' and Bayer's conduct, as alleged above, was malicious, fraudulent, and oppressive toward Plaintiffs in particular and the public generally, and Conceptus and Bayer conducted themselves in a willful and wanton manner by actively violating federal regulations.

1189. Conceptus and Bayer are guilty of malice, oppression, and fraud, and Plaintiffs are therefore entitled to recovery of exemplary or punitive damages in sum according to proof at trial.¹⁸⁰

¹⁸⁰ See, *Hutchison ex rel. Hutchison v. Luddy*, 582 Pa. 114, 870 A.2d 766 (2005) (The standard governing the award of punitive damages in Pennsylvania is well-settled: "Punitive damages may be awarded for

WHEREFORE, Plaintiffs respectfully demand judgment in an amount in excess of the Arbitration limits in Allegheny County against all Bayer Defendants, and each of them, individually, jointly and severally, and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

- A) compensatory damages for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;
- B) for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;
- C) for specific damages according to proof;
- D) for Punitive and Exemplary damages according to proof;
- E) for pre-judgment interest and post-judgment interest as allowed by law;
- F) for reasonable attorneys' fees;
- G) for the costs of these proceedings; and
- H) for such other and further relief as this Court deems just and proper.

A JURY TRIAL IS DEMANDED.

**THIRD CAUSE OF ACTION
Fraudulent Concealment
Fraudulent Omissions: Restat. 2d of Torts § 551**

1190. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

1191. Plaintiffs bring claims against Conceptus and Bayer under Pennsylvania law for fraudulent concealment / fraudulent omissions regarding the Essure[®] device.

conduct that is outrageous, because of the defendant's evil motive or his reckless indifference to the rights of others....[P]unitive damages are penal in nature and are proper only in cases where the defendant's actions are so outrageous as to demonstrate willful, wanton or reckless conduct").

A. CONCEPTUS AND BAYER HAD AFFIRMATIVE AND CONTINUING FEDERAL DUTIES TO NOT MAKE FRAUDULENT CONCEALMENTS AND/OR OMISSIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE®.

1192. Under the FDCA and FDA's implementing regulations, labeling and promotional advertisement claims about medical devices are deemed misleading if they fail to disclose certain information about the product's risks.

1193. The Essure® device that was implanted in Plaintiffs was promoted, distributed, manufactured and used in a manner that is in violation of federal law, the FDCA, the MDA, and regulations promulgated thereunder.

1194. It was the duty of Conceptus and Bayer to comply with federal law, the FDCA, the MDA and the regulations. Notwithstanding this duty, Conceptus and Bayer violated federal law, the FDCA, the MDA, and the regulations, including but not limited to, in one or more of, the following ways:

- A) Conceptus and Bayer had duties to not make false or misleading statements regarding Essure® under 21 U.S.C. §§ 331(a), 351 & 352(a), (q)&(r); 21 U.S.C. §§ 360(q)&(r); and 21 C.F.R. § 814.80.
- B) Conceptus and Bayer had duties to investigate and address adverse events under the following regulations: 21 C.F.R. § 820.3(z)(x); 21 C.F.R. § 820.22; 21 C.F.R. § 820.5; 21 C.F.R. § 820.1(a); 21 C.F.R. § 820.22; 21 C.F.R. § 820.100; 21 C.F.R. § 820.160(a); 21 C.F.R. § 820.198; 21 C.F.R. § 820.30; 21 C.F.R. § 803.3; 21 C.F.R. § 820.70 and 21 C.F.R. § 820.170(a).
- C) Conceptus and Bayer had duties to submit a PMA supplement and make a labeling change to add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association under 21 C.F.R. § 814.39, 21 C.F.R. § 803.56.
- D) Conceptus and Bayer had duties to report adverse events under 21 C.F.R. § 803.50; 21 C.F.R. § 814.80, and 21 U.S.C. § 360i(a).
- E) Conceptus and Bayer had duties to report new clinical investigations and/or scientific studies concerning the Essure® device about which Conceptus and Bayer knew or reasonably should have known about under 21 C.F.R. § 814.84(b)(2).

1195. The above regulations imposed duties on Conceptus and Bayer to accurately, timely, and honestly represent to the FDA, the public, Plaintiffs and Plaintiffs' physicians, the safety and effectiveness of Essure®.

B. CONCEPTUS AND BAYER HAD STATE DUTIES TO NOT MAKE FRAUDULENT CONCEALMENTS AND/OR OMISSIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE®.

1196. Pennsylvania cites specifically to Restatement (Second) of Torts § 551:

- (1) One who fails to disclose to another a fact that he knows may justifiably induce the other to act or refrain from acting in a business transaction is subject to the same liability to the other as though he had represented the nonexistence of the matter that he has failed to disclose, if, but only if, he is under a duty to the other to exercise reasonable care to disclose the matter in question.
- (2) One party to a business transaction is under a duty to exercise reasonable care to disclose to the other before the transaction is consummated,
 - (a) matters known to him that the other is entitled to know because of a fiduciary or other similar relation of trust and confidence between them; and
 - (b) matters known to him that he knows to be necessary to prevent his partial or ambiguous statement of the facts from being misleading; and
 - (c) subsequently acquired information that he knows will make untrue or misleading a previous representation that when made was true or believed to be so; and
 - (d) the falsity of a representation not made with the expectation that it would be acted upon, if he subsequently learns that the other is about to act in reliance upon it in a transaction with him; and
 - (e) facts basic to the transaction, if he knows that the other is about to enter into it under a mistake as to them, and that the other, because of the relationship between them, the customs of the trade or other objective circumstances, would reasonably expect a disclosure of those facts.¹⁸¹

¹⁸¹ *Duquesne Light Co. v. Westinghouse Elec. Corp.*, 66 F.3d 604 (3d Cir. 1995) (Acknowledging a duty to disclose in four circumstances: 1. When there is a fiduciary, or confidential, relationship between the parties; 2 When disclosure is necessary to prevent an ambiguous or partial statement from being misleading; 3. Where subsequently acquired knowledge makes a previous representation false; and 4. Where the undisclosed fact is basic to the transaction. The Pennsylvania elements of a claim for fraudulent omission are those stated in the Restatement 2d of Torts § 551, as cited in *Duquesne*.). See also, *Gibbs v. Ernst*, 647 A.2d 882, 892 (Pa. 1994).

C. CONCEPTUS' AND BAYER'S DUTY TO NOT MAKE FRAUDULENT CONCEALMENTS AND/OR OMISSIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE® UNDER PENNSYLVANIA LAW IS NOT DIFFERENT FROM OR IN ADDITION TO FEDERAL REQUIREMENTS.

1197. Under both Pennsylvania state and federal law, Conceptus and Bayer were under parallel duties not to make fraudulent concealments and/or omissions of material facts regarding the benefits and harms of the medical devices sold by them and were under parallel duties to disclose material facts regarding the benefits and harms of medical devices sold by them, specifically the Essure® device, to the FDA, Plaintiffs' physicians, and Plaintiffs, as detailed above in this Complaint.

1198. The state law and federal duties are identical because both prohibit these Defendants from making fraudulent concealments and/or omissions in the sale of their medical devices;¹⁸² thus, the state law cause of action alleged here is just one more reason for these Defendants to conform to their duties under the FDCA, the MDA, the Essure® PMA, and FDA Regulations.

1199. Conceptus and Bayer were required to comply with the duties listed in Section B. above, and were required to be truthful, accurate, and timely in performing the duties under federal law, as detailed above.

1200. Conceptus and Bayer had a continuing duty under the various regulations discussed above and per the terms of the PMA approval by the FDA to monitor its products after receiving FDA approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences and other such serious events of which they became aware. The duties to discover and report necessarily include the duties to not actively

¹⁸² See, FN 179, *supra*.

conceal and omit material health information of which it knew or should have known had it followed the federal regulations.

1201. Conceptus and Bayer failed to perform these duties under federal law, and thus failed to perform its duties under Pennsylvania law, as these Defendants had parallel duties to not conceal and omit material health information regarding the safety of the Essure® device to the FDA and other third parties.

1202. Pennsylvania law does not impose requirements that are different from, or in addition to requirements under federal law, and therefore Plaintiffs' claims are not preempted.

1203. Pennsylvania law exists independently of federal law. Here, Plaintiffs are not attempting to enforce federal law. Instead, Plaintiffs are seeking to hold Conceptus and Bayer liable for violating the state law duties to disclose material facts regarding the safety and efficacy of Essure®, which parallel federal regulations and requirements.

D. THERE IS A CAUSAL AND FACTUAL NEXUS BETWEEN PLAINTIFFS' INJURIES AND DEFENDANTS' BREACH OF ITS STATE LAW DUTIES, AND IDENTICAL FEDERAL REQUIREMENTS.

1204. Conceptus and Bayer breached its duties under federal and state laws by fraudulently omitting, concealing and misrepresenting the health and safety information about increased risks, dangers, hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with the Essure® device, as well as the relative benefits and availability of alternative procedures, to physicians including Plaintiffs' physicians.

1. Conceptus and Bayer Intentionally Concealed and/or Omitted Material Health and Safety Information Associated with Essure®.

1205. In connection with the Essure® product, Conceptus and Bayer intentionally concealed and/or omitted material and important health and safety product risk information to Plaintiffs and Plaintiffs' physicians, all as alleged in this Complaint.

1206. To protect sales and revenue, Conceptus and Bayer purposefully ignored their mandatory federal reporting requirements and actively hid safety information from the public.

1207. As detailed above, Conceptus knew of thousands of instances wherein the Essure® device had migrated in a woman or perforated a woman's organs and failed to report all of them.

1208. The FDA inspector cited Conceptus in 2003 for failing to adequately analyze all quality data sources to identify existing and potential causes of non-conforming products and other quality problems, and for failing to follow procedures for the control of products that do not conform to specifications.

1209. In June of 2008, the California Department of Public Health, Medical Device Safety Section ("CDPH") issued a Notice of Violation to Conceptus for failing to obtain a valid license to manufacture medical devices and failing to maintain procedure for inventory transfer.

1210. In December of 2010 the FDA inspector cited Conceptus for not reporting complaints of Essure® coils being seen inside the patients' abdominal cavity and not opening a CAPA when they became aware of these complaints. Conceptus was submitting MDRs and reporting complaints of the coils migrating into the peritoneal or abdominal cavity only if the patient was complaining of pain and a second procedure was required to remove the device.

1211. Conceptus concealed such complaints if the coil was subsequently removed during a laparoscopic tubal ligation surgery that was performed due to a failure of occlusion of the fallopian tubes.

1212. Conceptus concealed these adverse events, complaints and reports, and failed to follow adequate quality control procedures, investigate and analyze complaints, and open CAPAs, specifically to mislead physicians and women about the safety of the Essure® device.

1213. As detailed above, between January 1, 2008 and December 6, 2010, Conceptus received at least 16,581 complaints relating to Essure[®]. Of these 16,581 complaints, 16,399 were never reported to the FDA.

1214. Between May and June of 2013, the FDA conducted an inspection of Conceptus' Mountain View, CA facility which revealed 16,047 complaints Conceptus had received regarding Essure[®] between January 2011 and the date of the inspection. Of these 16,047 complaints, Conceptus withheld 15,712 from the FDA and the public.¹⁸³

1215. Further, and as detailed above, between Essure[®]'s inception in 2002 and through to 2016, the FDA received approximately 14,919 medical device reports (MDRs) related to safety problems with the device. Between 2016 and 2017, the FDA received an additional 11,854 MDRs.¹⁸⁴ Of those 26,773 MDRs, only 943 were made between 2002 and October 25, 2013. The FDA received the remaining reports between October 26, 2013 and December 31, 2017.¹⁸⁵

1216. The influx in MDR's is a result of the launch of the MedWatcher app, which allowed women to report their adverse events directly to the FDA.¹⁸⁶

1217. Prior to the MedWatcher app, women reported their adverse events directly to Conceptus, who actively concealed them from the FDA and the public, and/or omitted information from reporting.

1218. Conceptus and Bayer failed to adequately disclose to the FDA adverse events of which these manufacturers were informed after Essure[®]'s PMA approval.

¹⁸³ See <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/results.cfm>

¹⁸⁴ See

<https://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/essurepermanentbirthcontrol/ucm452254.htm> (last updated March 7, 2018).

¹⁸⁵ See *id.*

¹⁸⁶ See "Increasing Patient Engagement in Pharmacovigilance Through Online Community Outreach and Mobile Reporting Applications: An Analysis of Adverse Event Reporting for the Essure Device in the US" available online at: <http://link.springer.com/article/10.1007/s40290-015-0106-6/fulltext.html> (last visited January 31, 2018).

1219. As detailed above, this significant increase prompted the FDA to convene a meeting of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee on September 24, 2015 to examine safety concerns about Essure[®] raised by patients and cited in MDRs, and on February 29, 2016 to announce that it will require a major change to the Essure[®] warning label and also require all women considering Essure[®] placement to fill out a Patient Decision Checklist” to ensure that they are fully informed of the true risks, and on November 15, 2016 to approve changes for physician instructions for use, and a patient information booklet including a boxed warning and patient decision checklist.¹⁸⁷

1220. Due to Conceptus’ and Bayer’s failure to report adverse events when they had a duty to speak, the labeling originally approved by the FDA for Essure[®] became false before the Plaintiffs’ surgeries and thus failed to protect the public health by failing to adequately disclose the harms, risks and benefits of Essure[®].

1221. Had Conceptus and Bayer timely and accurately reported adverse events and implemented quality control procedures and CAPAs to investigate and analyze complaints associated with Essure[®], instead of actively concealing and/or omitting material safety information in their required reporting to the FDA, the “Black Box Warning” and “Patient Decision Checklist” would have come out earlier and effectively warned Plaintiffs and their physicians.

2. Conceptus and Bayer Fraudulently Concealed and/or Omitted the Risks of Essure[®] as Compared to Alternative Methods of Permanent Sterilization.

1222. Conceptus and Bayer represented that Essure[®] had the following “key advantages” over laparoscopic tubal ligation: transcervical placement, local IV sedation, 45 minutes of average

¹⁸⁷ See <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm488313.htm> (last visited January 31, 2018); and see <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020014S046> (last visited January 31, 2018).

post-op recovery, procedure performance in an outpatient/hospital, surgical center or doctor's office, and a 1-2-day average wait time to return to regular activities.

1223. Conceptus concealed from the public that most of the adverse events reported by patients with Essure[®] were for injuries that would require and did require a subsequent surgical operation.

1224. When the BMJ study, *Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study*,¹⁸⁸ found that women who used Essure[®] as a means for permanent sterilization are ten times more likely to undergo re-operation within one year of the initial procedure due to device related complications and injuries compared to women who undergo tubal ligation, Conceptus and Bayer did not submit any MDR reportable events derived from this study to the FDA.

1225. In March of 2014 the authors of *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization*¹⁸⁹ concluded that at all points in time after the sterilization procedure, the initial and cumulative risk of pregnancy after sterilization is higher in women who undergo hysteroscopic sterilization than either laparoscopic band or bipolar sterilization. Bayer and Conceptus continued the pattern of concealment by omitting this information from their promotion of Essure[®] as a more effective option than tubal ligation.

1226. Conceptus and Bayer marketed Essure[®] as the "only FDA approved female sterilization procedure to have zero pregnancies in the clinical trials," and concealed and/or omitted information regarding the four pregnancies during the clinical trials and five pregnancies

¹⁸⁸ See "Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study" available online at: <http://www.bmj.com/content/351/bmj.h5162> (last visited January 31, 2018).

¹⁸⁹ See "Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization" available at: <http://www.contraceptionjournal.org/pb/assets/raw/Health%20Advance/journals/contra/CON-8309-FINAL.pdf> (last visited January 31, 2018).

during the first year of commercial experience. A recent study indicates that women implanted with Essure® have a *ten times* greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four times greater.

1227. Instead of disclosing these risks, Conceptus and Bayer intentionally concealed and/or omitted this information from their patient brochures and promotional information.

3. As a Direct, Proximate and Causal Result of Conceptus' and Bayer's Fraudulent Concealments and/or Omissions, Plaintiffs Sustained Substantial Injuries.

1228. Conceptus and Bayer knew, or should have known, that they were concealing, suppressing, and misrepresenting true information about the known increased risks and benefits of the use of Essure® and the relative benefits and availability of alternate procedures.

1229. Conceptus and Bayer knew that Plaintiffs and Plaintiffs' physicians would regard the matters that they concealed, suppressed, and misrepresented to be important in determining the course of treatment for the Plaintiffs, including Plaintiffs' and Plaintiffs' physicians' decisions to use Essure® as a method of permanent sterilization.

1230. Conceptus and Bayer intended to cause Plaintiffs and Plaintiffs' physicians to rely on their concealment of material safety information, suppression, and misrepresentations about the increased risks and dangers related to Essure® as a method of permanent sterilization.

1231. Plaintiffs and Plaintiffs' physicians were justified in relying, and did rely, on Conceptus' and Bayer's concealment of information and misrepresentations about the increased safety risks and dangers related to Essure® in deciding to recommend and choose the Essure® procedure for permanent sterilization.

1232. As a direct and proximate result of Conceptus' and Bayer's fraudulent concealment, suppression, and misrepresentations of material increased health and safety risks and dangers relating to Essure®, and Conceptus' and Bayer's promotion and marketing practices, Plaintiffs

suffered injuries and economic loss, and Plaintiffs will continue to suffer injuries, damages and economic loss.

1233. As the direct, proximate, and legal cause and result of Conceptus' and Bayer's false and deceptive marketing and promotion practices related to Essure®, Plaintiffs have been injured and have incurred damages, including but not limited to medical and hospital expenses, physical and mental pain and suffering, and loss of the enjoyment of life.

1234. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

1235. Conceptus' and Bayer's conduct, as alleged above, was malicious, oppressive, intentional, reckless and/or outrageous, and constituted willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and warrants an award of punitive damages.

WHEREFORE, Plaintiffs respectfully demand judgment in an amount in excess of the Arbitration limits in Allegheny County against all Bayer Defendants, and each of them, individually, jointly and severally, and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

- A) compensatory damages for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;
- B) for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;
- C) for specific damages according to proof;
- D) for Punitive and Exemplary damages according to proof;
- E) for pre-judgment interest and post-judgment interest as allowed by law;
- F) for reasonable attorneys' fees;

G) for the costs of these proceedings; and

H) for such other and further relief as this Court deems just and proper.

A JURY TRIAL IS DEMANDED.

**FOURTH CAUSE OF ACTION
Negligent Misrepresentation
Restat. 2d of Torts, § 552**

1236. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

1237. Plaintiffs bring a claim against Conceptus and Bayer under Pennsylvania law for negligent misrepresentation regarding the Essure® device.

A. CONCEPTUS AND BAYER HAD AFFIRMATIVE AND CONTINUING FEDERAL DUTIES TO NOT MAKE MISREPRESENTATIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE®.

1238. Plaintiffs incorporate by reference herein the allegations stated in the Second Cause of Action, section A, above.

1239. The Essure® device that was implanted in Plaintiffs was promoted, distributed, manufactured and used in a manner that is in violation of federal law, the FDCA, the MDA, and regulations promulgated thereunder.

1240. Under the FDCA and FDA's implementing regulations, labeling and promotional advertisements about medical devices are deemed misleading if they fail to disclose certain information about the product's risks.

1241. It was the duty of Conceptus and Bayer to comply with federal law, the FDCA, the MDA and the regulations, notwithstanding this duty, Conceptus and Bayer violated federal law, the FDCA, the MDA, and the regulations.

B. CONCEPTUS AND BAYER HAD STATE DUTIES TO NOT MAKE MISREPRESENTATIONS OF MATERIAL FACTS REGARDING THE BENEFITS AND HARMS OF ESSURE®.

1242. Pennsylvania follows Section 552 of the Restatement (Second) of Torts to determine liability of a commercial product seller or distributor for harm resulting from negligent misrepresentation:

- (1) One who, in the course of his business, profession or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.
- (2) Except as stated in Subsection (3), the liability stated in Subsection (1) is limited to loss suffered
 - (a) by the person or one of a limited group of persons for whose benefit and guidance he intends to supply the information or knows that the recipient intends to supply it; and
 - (b) through reliance upon it in a transaction that he intends the information to influence or knows that the recipient so intends or in a substantially similar transaction.
- (3) The liability of one who is under a public duty to give the information extends to loss suffered by any of the class of persons for whose benefit the duty is created, in any of the transactions in which it is intended to protect them.^{190, 191}

¹⁹⁰ See *Bilt-Rite Contrs., Inc., v. Architectural Studio*, 866 A.2d 270 (Pa. 2005) (adopting Restatement (Second) of Torts § 552; and see *Rich v. Brandywine Ins. Advisors, LLC*, 2017 U.S. Dist. LEXIS 34404, *15 (E.D. PA. Mar. 9, 2017) (The Third Circuit in *Rich* recognized that the Pennsylvania Supreme Court adopted Restatement (Second) of Torts § 552).

¹⁹¹ *Gibbs v. Ernst*, 647 A.2d 882, 890 (Pa. 1994) (The elements which must be proven for negligent misrepresentation include: (1) a misrepresentation of a material fact; (2) the representor must either know of the misrepresentation, must make the misrepresentation without knowledge as to its truth or falsity or must make the representation under circumstances in which he ought to have known of its falsity; (3) the representor must intend the representation to induce another to act on it; and (4) injury must result to the party acting in justifiable reliance on the misrepresentation) (internal citations omitted).

C. CONCEPTUS' AND BAYER'S DUTY TO NOT TO MAKE NEGLIGENT MISREPRESENTATIONS UNDER PENNSYLVANIA LAW IS NOT DIFFERENT FROM OR IN ADDITION TO FEDERAL REQUIREMENTS.

1243. Under both Pennsylvania state and federal law, Conceptus and Bayer were under parallel duties not to make negligent or other misrepresentations of material facts regarding the benefits and harms of the medical devices sold by them. The state law and federal duties are identical because both prohibit these Defendants from making misrepresentations in the sale of their medical devices;¹⁹² thus, the state law cause of action alleged here is just one more reason for these Defendants to conform to their duties under the FDCA, the MDA, the Essure® PMA, and FDA Regulations.

1244. Conceptus and Bayer were required to comply with the duties listed in Section B. above, and were required to be truthful, accurate, and timely in performing the duties under federal law, as detailed above.

1245. Pennsylvania law does not impose requirements that are different from, or in addition to requirements under federal law, and therefore Plaintiffs' claims are not preempted.

1246. Pennsylvania law exists independently of federal law. Here, Plaintiffs are not attempting to enforce federal law. Instead, Plaintiffs are seeking to hold Conceptus and Bayer liable for violating the state law duties to not make false and misleading statements regarding Essure®, which parallel federal regulations and requirements.

D. THERE IS A CAUSAL AND FACTUAL NEXUS BETWEEN PLAINTIFFS' INJURIES AND DEFENDANTS' BREACH OF THEIR STATE LAW DUTIES AND IDENTICAL FEDERAL REQUIREMENTS.

1247. Plaintiffs incorporate by reference the allegations stated in the Second Cause of Action, section D, above.

¹⁹² See FN 149, *supra*.

1248. Conceptus and Bayer breached their duties under federal and state laws, as follows:

- A) Negligently misrepresented the health and safety hazards, symptoms, diseases and/or health problems associated with use of Essure® for the purposes intended by these Defendants;
- B) Negligently misrepresented their illegal, improper and unethical schemes to promote and market Essure® as “simple” and “worry-free”; and
- C) Negligently misrepresented information about the known comparative risks and benefits of the use of Essure® and the relative benefits and availability of alternate products, treatments and/or therapies.

1. Conceptus and Bayer Negligently Misrepresented the Health and Safety Information Associated with Essure®.

1249. Plaintiffs incorporate by reference the allegations stated in the Second Cause of Action, section D (1), above.

1250. In connection with the Essure® product, Conceptus and Bayer failed to exercise reasonable care in ascertaining the accuracy of important health and safety information and/or the manner in which it is communicated to Plaintiffs and Plaintiffs’ physicians, all as alleged in this Complaint.

1251. As medical device manufacturers, Conceptus and Bayer had a duty to use reasonable care ascertaining the accuracy of material health and safety information about the Essure® device, and in the presentation and communication of such information to the public, Plaintiffs and Plaintiffs’ physicians.

1252. Had Conceptus and Bayer complied with their duties to the FDA as described under the FDCA and detailed above in this Complaint, which are parallel to their state law duties, the necessary and resultant actions by the FDA and/or appropriate government agencies would have precluded the use of the product by Plaintiffs and Plaintiffs’ physicians.

2. Conceptus and Bayer Made Negligent Misrepresentations Regarding the Safety and Efficacy of Essure® Through Marketing.

1253. Plaintiffs incorporate by reference the allegations stated in the Second Cause of Action, section D (2), above.

1254. Conceptus conducted enormous and aggressive marketing campaigns that disseminated false and misleading statements pertaining to the convenience, safety and efficacy of the device.

3. Conceptus and Bayer Negligently Misrepresented the Comparative Risks and Benefits of Essure® to Alternative Methods of Permanent Sterilization.

1255. Plaintiffs incorporate by reference herein the allegations stated in the Second Cause of Action, Section D (3), above.

1256. Conceptus misrepresented that Essure® had “key advantages” over laparoscopic tubal ligation, as alleged in the Second Cause of Action, Section D (3).

4. As a Direct, Proximate and Causal Result of Conceptus’ and Bayer’s Negligent Misrepresentations, Plaintiffs Sustained Substantial Injuries.

1257. Conceptus engaged in the above activities which influenced the public’s knowledge of safety risks associated with Essure® and exposed patients to serious dangers and greatly increased adverse risks.

1258. Conceptus and Bayer negligently misrepresented to the FDA, the public, Plaintiffs and Plaintiffs’ physicians the benefits and harms associated with Essure®.

1259. Such misrepresentations corrupted resources available to surgeons, like Plaintiffs’ implanting surgeons, regarding the safety and effectiveness of Essure®.

1260. Plaintiffs’ implanting physicians relied on such misrepresentations, thus subjecting their patients, including Plaintiffs, to an unreasonable risk of physical harm.

1261. Due to Conceptus' and Bayer's negligence, Plaintiffs' physicians and Plaintiffs did not have the necessary information in order to make an informed decision in the best interests of Plaintiffs' health.

1262. Conceptus and Bayer provided inaccurate, false, or misleading information which was material to Plaintiffs' implanting physicians' treatment decisions, which misled Plaintiffs' physicians and Plaintiffs who were relying on their physicians' professional judgment.

1263. When Conceptus and Bayer made the above representations, they did so without any regard for the accuracy of the information presented, or the manner in which the information was communicated.

1264. Had the FDA known of the actual dangers of and inefficacy of the use of Essure[®], they would have initiated a recall of the product, dear doctor letter, safety signal and/or warned the public of the danger.

1265. At the time the aforesaid representations were made by Conceptus and Bayer, Plaintiffs and their medical providers were unaware of the falsity of said representations and reasonably relied upon Conceptus' and Bayer's assertions, that the Essure[®] device was safe when in fact it was not.

1266. In reliance upon Conceptus' and Bayer's representations, Plaintiffs and Plaintiffs' physicians used Essure[®].

1267. Plaintiffs and Plaintiffs' physicians were justified in their reliance on Conceptus' and Bayer's representations and marketing. Plaintiffs actually did undergo the Essure[®] implant procedure, which ultimately caused Plaintiffs' physical injuries.

1268. As a direct and proximate result of said misrepresentations, Plaintiffs have been injured and have incurred damages, including but not limited to medical and hospital expenses,

lost wages and lost earning capacity, physical and mental pain and suffering, and loss of the enjoyment of life.

1269. Had Plaintiffs' implanting physicians and Plaintiffs been made fully and adequately aware of the inefficacy and serious increased risks and dangers associated with such use, as well as Bayer's and Conceptus' failure to investigate and analyze adverse events and/or implement CAPAs, Plaintiffs' physicians would not have recommended Essure® to Plaintiffs, and Plaintiffs would not have chosen to have Essure® implanted in their fallopian tubes.

WHEREFORE, Plaintiffs respectfully demand judgment in an amount in excess of the Arbitration limits in Allegheny County against all Bayer Defendants, and each of them, individually, jointly and severally, and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

- A) compensatory damages for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;
- B) for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;
- C) for specific damages according to proof;
- D) for Punitive and Exemplary damages according to proof;
- E) for pre-judgment interest and post-judgment interest as allowed by law;
- F) for reasonable attorneys' fees;
- G) for the costs of these proceedings; and
- H) for such other and further relief as this Court deems just and proper.

A JURY TRIAL IS DEMANDED.

FIFTH CAUSE OF ACTION
Negligent Training

1270. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

1271. Plaintiffs bring claims against Conceptus and Bayer under Pennsylvania law for Negligent Training regarding the Essure[®] device.

1272. In order to capture the market, Conceptus and Bayer independently undertook a duty of training physicians, including Plaintiffs' implanting physicians, on (1) the safe and proper use of the Essure[®] procedure; (2) how to properly use its own mechanism of delivery; and (3) the specialized hysteroscopic equipment manufactured by a third party.

1273. The PMA approval sets forth Conceptus' and Bayer's duty to train physicians, and a manufacturer/applicant is required to comply with the standards and conditions set forth in the PMA approval letter.¹⁹³

1274. Conceptus and Bayer had a parallel duty under Pennsylvania law to exercise reasonable care in their training of physicians to avoid foreseeable injury.¹⁹⁴

1275. Under both Pennsylvania state and federal law, Conceptus and Bayer were under parallel duties to use reasonable care in the training of physicians on the safe and proper use of the Essure[®] device. The state law and federal duties are identical; thus, the state law cause of action alleged here is just one more reason for these Defendants to conform to their duties under the FDCA, the MDA, the Essure[®] PMA, and FDA Regulations.

¹⁹³ 21 C.F.R. § 814.80 (2012).

¹⁹⁴ *Seebold v. Prison Health Sys., Inc.*, 57 A.3d 1232, 1244-45 (Pa. 2012) (citing Restatement (Second) of Torts § 324A). Further, in Pennsylvania, a party claiming harm resulting from negligence must generally establish: (1) a duty owed to the plaintiff by the defendant; (2) a breach of that duty; (3) a causal connection between the breach and the resulting injury; and (4) actual loss or damages.

1276. Pennsylvania law does not impose requirements that are different from, or in addition to requirements under federal law, and therefore Plaintiffs' claims are not preempted.

1277. Pennsylvania law exists independently of federal law. here, Plaintiffs are not attempting to enforce federal law. Instead, Plaintiffs are seeking to hold Conceptus and Bayer liable for violating the state law duties to use reasonable care in the training of physicians on the proper use of Essure[®], which parallel federal regulations and requirements.

1278. Conceptus and Bayer breached their duties under the PMA and federal law to train physicians on the safe and proper use of Essure[®].

1279. Conceptus and Bayer breached their duties under Pennsylvania law, as follows:

- Conceptus and Bayer were negligent in choosing not to take reasonable steps in developing an adequate training program for the Essure[®] procedure, educating employees to properly train physician users on the safe and proper methods of the Essure[®] procedure, and supervising employees while training physician users on the safe and proper methods of the Essure[®] procedure.
- Conceptus and Bayer were negligent in not safely and properly training Plaintiffs' implanting physicians on how to safely and properly perform the Essure[®] procedure.

1280. Conceptus and Bayer (1) undertook a duty to train physicians on the safe and proper use of the Essure[®] procedure; (2) failed to adequately train the physicians on how to use its delivery system and the hysteroscopic equipment manufactured by a third party; (3) provided specialized hysteroscopic equipment to implanting physicians who were not qualified to use the same; and (4) it was foreseeable that Conceptus and Bayer's negligent training program would cause harm to Plaintiffs.

1281. Conceptus and Bayer engaged in the above activities which exposed patients, including Plaintiffs, to serious dangers and greatly increased adverse risks.

1282. Conceptus and Bayer failed to properly train Plaintiffs' implanting physicians on proper management of post-implant complications.

1283. Conceptus and Bayer failed to properly train Plaintiffs' implanting physicians on how to safely and effectively remove the Essure[®] coils once the implant procedure was completed.

1284. Conceptus and Bayer failed to properly train Plaintiffs' implanting physicians on how to use its delivery system and the hysteroscopic equipment.

1285. Despite Conceptus' and Bayer's failure to train Plaintiffs' implanting physicians, these Defendants "signed-off" on Plaintiffs' implanting physicians and provided specialized hysteroscopic equipment to them to perform Essure[®] procedures.

1286. Due to Conceptus' and Bayer's negligence, Plaintiffs' physicians and Plaintiffs did not have the necessary information in order to make an informed decision in the best interests of Plaintiffs' health.

1287. Had Conceptus and Bayer implemented a training program on the safe and proper methods of implanting Essure[®] prior to Plaintiffs' surgeries, their physicians would have adequately performed their implants.

1288. As a proximate and legal result of these Defendants' failure to properly discharge a duty it undertook to train physicians, Plaintiffs' implanting physicians did not adequately perform Plaintiffs' implants.

1289. Instead, Plaintiffs' implants were improperly performed, causing the coils to migrate and/or perforate Plaintiffs' organs. Plaintiffs suffered severe pain and bleeding without proper management of these post-implant complications; and Plaintiffs required subsequent surgeries as a result of their implanting physicians' improper performance of the Essure[®] procedure.

1290. As a proximate and legal result of these Defendants' failure to properly discharge a duty it undertook to train physicians, they breached their duty of care to Plaintiffs under Pennsylvania law and caused Plaintiffs injuries, including but not limited to medical and hospital expenses, lost wages and lost earning capacity, physical and mental pain and suffering, and loss of the enjoyment of life.

WHEREFORE, Plaintiffs respectfully demand judgment in an amount in excess of the Arbitration limits in Allegheny County against all Bayer Defendants, and each of them, individually, jointly and severally, and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

- A) compensatory damages for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;
- B) for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;
- C) for specific damages according to proof;
- D) for Punitive and Exemplary damages according to proof;
- E) for pre-judgment interest and post-judgment interest as allowed by law;
- F) for reasonable attorneys' fees;
- G) for the costs of these proceedings; and
- H) for such other and further relief as this Court deems just and proper.

A JURY TRIAL IS DEMANDED.

SIXTH CAUSE OF ACTION
Negligent Failure to Test¹⁹⁵
Restat. 2d of Torts § 398

1291. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

1292. Under both state and federal law, these Defendants were under parallel duties to conform to the PMA approval process. This process is designed to prevent a manufacturer from introducing into the stream of commerce a medical device that has *not* been tested in adequately designed clinical trials and which has *not* otherwise passed a rigorous scientific review to determine that such a device is safe and effective for the use intended by the manufacturer.

1293. In this regard, the manufacturers' duties of due care under Pennsylvania state law and its federal duties pursuant to FDA rules and regulations are identical. Both prohibit these Defendants from marketing untested devices, which are unreasonably dangerous; thus, the state law cause of action alleged here is just one more reason for these Defendants to conform to their duties under federal law.

1294. Defendants marketed the Essure[®] device to and for the benefit of Plaintiffs.

1295. Defendants owed Plaintiffs, and their physicians, duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing scientific knowledge at the time the product was sold.

1296. This is also a parallel violation of the duty of due care under the Pennsylvania negligence rule of reasonable care, which requires a manufacturer to take ordinary and reasonable care before marketing such devices by submitting them to adequately designed clinical testing for

¹⁹⁵ *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014), see also, *Maya v. Benefit Risk Mgmt.*, 2012 Phila. Ct. Com. Pl. LEXIS 449, citing *Wyeth v. Levine*, 555 U.S. 555 129 S. Ct. 1187(2009) (placing responsibility for post-market surveillance on the manufacturer).

safety and effectiveness. Such testing is reasonably necessary and ordinarily prudent in order to prevent the distribution of unreasonably dangerous products into the market place.¹⁹⁶

1297. At the time of Plaintiffs' implants, Conceptus and Bayer failed to perform adequately designed clinical testing of Essure[®] as required under its PMA and supplements, federal regulations and parallel state law.

1298. A new post-marketing study was required as a condition of the Essure[®] 2007 premarketing approval supplement.¹⁹⁷

1299. Nevertheless, Conceptus and Bayer intended to and did promote and market Essure[®] as a safe and effective device and did distribute this unreasonably dangerous device to Plaintiffs and Plaintiffs' implanting physicians without completing the required postmarket study.

1300. "This study was never registered at ClinicalTrials.gov, despite the 2007 FDA Amendments Act requirement, and was stopped early at the manufacturer's request after 578 [of the 800 required] underwent attempted implantation. Its findings are minimally informative, since no follow-up data were collected and nearly all study results reported on the FDA website are redacted."¹⁹⁸

1301. One purpose of this aborted study was to determine adverse effects potentially related to the device, however it is clear from the limited data available on the FDA website that no follow-up visits occurred based on the adverse event findings and "N/A" listed next to "Followup Visits and Length of Followup."¹⁹⁹

¹⁹⁶ 21 U.S.C. §§ 351 and 352; Pennsylvania Common Law, 35 P.S. § 780-108.

¹⁹⁷ See "Revisiting Essure – Toward Safe and Effective Sterilization" available online at: <http://www.nejm.org/doi/full/10.1056/NEJMp1510514>

¹⁹⁸ *Id.*

¹⁹⁹ See http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?c_id=112&t_id=367828

1302. The Essure® device marketed and distributed by Conceptus and Bayer was misbranded because their FDA-approved labeling was inadequate to convey the true safety and effectiveness information as marketed by these Defendants.

1303. The distribution of these misbranded devices is a violation of federal law because of the failure to conform to procedures required by the PMA Supplement approval.

1304. 33Plaintiffs were harmed by Conceptus and Bayer's marketing and distribution of a misbranded device, with an inaccurate risk/benefit profile.

1305. Conceptus and Bayer could have discovered the defective condition of Essure®, but failed to conduct and complete adequate tests and inspections that would have disclosed the defects.

1306. Conceptus and Bayer failed to exercise reasonable care in adequately testing and completing such testing of the Essure® device subject to the 2007 PMA supplement.

1307. Conceptus and Bayer knew, or should have known, that due to their failure to use reasonable care, Plaintiffs and their physicians would use and did use Essure® to the detriment of Plaintiffs' health, safety and well-being.

1308. As the direct, producing, proximate and legal result of these Defendants' negligence, Plaintiffs have suffered severe physical pain, medical and hospital expenses, lost wages, pain and suffering, and pecuniary loss.

1309. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

WHEREFORE, Plaintiffs respectfully demand judgment in an amount in excess of the Arbitration limits in Allegheny County against all Bayer Defendants, and each of them, individually, jointly and severally, and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

- A) compensatory damages for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;
- B) for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;
- C) for specific damages according to proof;
- D) for Punitive and Exemplary damages according to proof;
- E) for pre-judgment interest and post-judgment interest as allowed by law;
- F) for reasonable attorneys' fees;
- G) for the costs of these proceedings; and
- H) for such other and further relief as this Court deems just and proper.

A JURY TRIAL IS DEMANDED.

SEVENTH CAUSE OF ACTION

Breach of Express Warranty

13 Pa. Cons. Stat. § 2313

1310. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

1311. Conceptus and Bayer utilized journal articles, advertising media, and sales representatives to promote, encourage, and urge the use and purchase of the Essure® device, representing the quality to health care professionals, the FDA, Plaintiffs, and the public in such a way as to induce its purchase or use, thereby making an express warranty that Essure® would conform to the representations.

1312. More specifically, Plaintiffs incorporate by reference herein the allegations stated in the Second Cause of Action, section D (1-3), above.

1313. Additionally, Conceptus Inc. represented that Essure® was the “most effective permanent birth control method available”²⁰⁰ when it introduced the Essurance Promise Program, which was a patient reliance program. According to Conceptus, this was an “out-of-pocket” payment assistance program for the Essure® confirmation HSG test. If the patient was told at the time of her HSG test that the Essure® procedure requires more time to be effective, or that the patient cannot rely on Essure for permanent birth control, Conceptus represented that they would pay up to \$150 for the test. Conceptus further represented that “[n]o other method of permanent birth control works better than the Essure® procedure and no company other than Conceptus backs up their procedure with a reliance warranty, which gives women full confidence in this birth control choice.”

1314. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

1315. Essure® did not conform to the representations made by Conceptus and Bayer, as the Essure® device was not safe and effective and was not safe and effective for use by individuals such as Plaintiffs.

1316. At all relevant times, Plaintiffs used Essure® for the purpose and in the manner intended by Conceptus and Bayer.

1317. Plaintiffs and Plaintiffs’ physicians, by the use of reasonable care, could not have discovered the breached warranty and realized Essure®’s hidden increased risks and its unreasonable dangers.

²⁰⁰ See <https://globenewswire.com/news-release/2011/05/02/445842/220416/en/Conceptus-R-Introduces-the-Only-Patient-Reliance-Warranty-for-Permanent-Birth-Control.html> (last visited February 27, 2018).

1318. Defendants' breaches constitute violations of state common laws, including but not limited to, the following statutory provisions: 13 Pa. Cons. Stat. § 2313.²⁰¹

1319. The breach of the warranty was a substantial factor in bringing about Plaintiffs' injuries.

1320. Conceptus and Bayer intended to induce Plaintiffs and their physicians to rely on their misrepresentations to use Essure[®] over the alternative methods of permanent sterilization.

1321. In reliance upon Conceptus' and Bayer's representations, Plaintiffs and Plaintiffs' physicians used Essure[®].

1322. Plaintiffs and Plaintiffs' physicians were justified in their reliance on Conceptus' and Bayer's representations and marketing. Plaintiffs actually did undergo the Essure[®] implant procedure, which ultimately caused Plaintiffs' serious physical injury.

1323. As a direct and proximate result of said misrepresentations, Plaintiffs have been injured and have incurred damages, including but not limited to medical and hospital expenses, lost wages and lost earning capacity, physical and mental pain and suffering, and loss of the enjoyment of life.

1324. Had Plaintiffs' implanting physicians and Plaintiffs been made fully and adequately aware of the inefficacy and serious increased risks and dangers associated with such use, Plaintiffs' physicians would not have recommended Essure[®] to Plaintiffs, and Plaintiffs would not have chosen to have Essure[®] implanted in their fallopian tubes.

²⁰¹ (1) Express warranties by the seller are created as follows: (1) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise. (2) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description. (3) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model. 13 Pa. Cons. Stat. § 2313.

WHEREFORE, Plaintiffs respectfully demand judgment in an amount in excess of the Arbitration limits in Allegheny County against all Bayer Defendants, and each of them, individually, jointly and severally, and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

- A) compensatory damages for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;
- B) for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;
- C) for specific damages according to proof;
- D) for Punitive and Exemplary damages according to proof;
- E) for pre-judgment interest and post-judgment interest as allowed by law;
- F) for reasonable attorneys' fees;
- G) for the costs of these proceedings; and
- H) for such other and further relief as this Court deems just and proper.

A JURY TRIAL IS DEMANDED.

EIGHTH CAUSE OF ACTION

Strict Liability

Restat. 2d of Torts § 402A

1325. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

A. PLAINTIFFS HAVE A CAUSE OF ACTION UNDER *TINCHER V. OMEGA FLEX* AND THE RESTATEMENT (SECOND) OF TORTS § 402A.²⁰²

1326. Pennsylvania common law governs claims or actions brought for personal injury,

²⁰² *Tincher v. Omega Flex*, 104 A.3d 328 (Pa. 2014) (overruling *Azzarello v. Black Brothers Co.*, 391 A.2d 1020 (Pa. 1978)). See also, *Phillips v. A-Best Prods. Co.*, 665 A.2d 1167 (Pa. 1995) (recognizing design defect, Manufacturing defect and failure to warn strict liability claims).

death or property damage caused by or resulting from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, testing, certifying, warning, instructing, marketing, advertising, packaging, or labeling of any product.

1327. Pennsylvania Supreme Court has adopted Section § 402A of the Restatement (Second) of Torts²⁰³ and permits a claim or portion of a claim in which the plaintiff seeks relief in the form of damages on a theory that the defendant is strictly liable for such damages because: (1) Conceptus and Bayer, wherever situated in the chain of commerce, transferred a product in the course of their business; and (2) The product was used in a manner reasonably anticipated; and (3) Either or both of the following: (a) The product was then in a defective condition and unreasonably dangerous when put to a reasonably anticipated use, and the Plaintiffs were damaged as a direct result of such defective condition that existed when the product was sold; or (b) The product was then unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics, and the Plaintiffs were damaged as a direct result of the product being sold without an adequate warning.

1328. The Essure[®] device that was implanted in Plaintiffs was promoted, distributed, manufactured and used in a manner that is in violation of federal law, the FDCA, the MDA, and regulations promulgated thereunder, and parallel state law.

1329. Pennsylvania law does not impose requirements that are different from, or in addition to requirements under federal law, and therefore Plaintiffs' claims are not preempted.

1330. The state law and federal duties are identical; thus, the state law cause of action alleged here is just one more reason for these Defendants to conform to their duties under the FDCA, the MDA, the Essure[®] PMA, and FDA Regulations.

²⁰³ *Id.*

1331. Pennsylvania law exists independently of federal law. Here, Plaintiffs are not attempting to enforce federal law. Instead, Plaintiffs are seeking to hold Conceptus and Bayer liable for violating the state law duties, which parallel federal regulations and requirements.

1. Conceptus and Bayer Failed to Comply with the Following Federal Requirements Regarding Essure®.

1332. Conceptus and Bayer at all times herein were medical device manufacturers and subject to duties under the PMA, FDCA and various federal regulations.

1333. Conceptus and Bayer designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Essure®, including the Essure® devices that were implanted into Plaintiffs.

1334. It was the duty of Conceptus and Bayer to comply with federal law, the FDCA, the MDA and the regulations.

1335. Conceptus and Bayer had duties to not make false or misleading statements regarding Essure® under 21 U.S.C. §§ 331(a), 351 & 352(a),(q)&(r); 21 U.S.C. §§ 360(q)&(r); and 21 C.F.R. § 814.80. Conceptus and Bayer breached these duties as stated in this Complaint, specifically the First Cause of Action, Second Cause of Action, Third Cause of Action, Fourth Cause of Action, and Seventh Cause of Action, which are incorporated by reference herein.

1336. Conceptus and Bayer had duties to investigate and address adverse events under the following regulations: 21 C.F.R. § 820.3(z)(x); 21 C.F.R. § 820.22; 21 C.F.R. § 820.5; 21 C.F.R. §820.1(a); 21 C.F.R. § 820.22; 21 C.F.R. § 820.100; 21 C.F.R. § 820.160(a); 21 C.F.R. § 820.198; 21 C.F.R. § 820.30; 21 C.F.R. § 803.3; 21 C.F.R. § 820.70 and 21 C.F.R. § 820.170(a). Conceptus and Bayer breached these duties as stated in this Complaint, specifically the First Cause of Action, Second Cause of Action, Third Cause of Action, Fourth Cause of Action, and Seventh Cause of Action, which are incorporated by reference herein.

1337. Conceptus and Bayer had duties to submit a PMA supplement and make a labeling change to add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association under 21 C.F.R. § 814.39, 21 C.F.R. § 803.56. Conceptus and Bayer breached these duties as stated in this Complaint, specifically the First Cause of Action, Second Cause of Action, Third Cause of Action and Fourth Cause of Action, which are incorporated by reference herein.

1338. Conceptus and Bayer had duties to report adverse events under 21 C.F.R. § 803.50; 21 C.F.R. § 814.80, 21 C.F.R. § 814.84(b)(2) and 21 U.S.C. § 360i(a). Conceptus and Bayer breached these duties as stated in this Complaint, specifically the First Cause of Action, Second Cause of Action, Third Cause of Action and Fourth Cause of Action, which are incorporated by reference herein.

1339. Conceptus and Bayer had duties to report new clinical investigations and/or scientific studies concerning the Essure[®] device about which Conceptus and Bayer knew or reasonably should have known about under 21 C.F.R. § 814.84(b)(2). Conceptus and Bayer breached these duties as stated in this Complaint, specifically the First Cause of Action, Second Cause of Action, Third Cause of Action and Fourth Cause of Action, which are incorporated by reference herein.

1340. Conceptus and Bayer had duties to comply with quality control standards under 21 C.F.R. § 820.3(z)(x); 21 C.F.R. § 820.22; 21 C.F.R. § 820.5; 21 C.F.R. § 820.1(a); 21 C.F.R. § 820.22; 21 C.F.R. § 820.160(a); 21 C.F.R. § 820.198(a) and 21 C.F.R. § 820.170(a). Conceptus and Bayer breached these duties as stated in this Complaint, specifically the First Cause of Action, Second Cause of Action, Third Cause of Action and Fourth Cause of Action which are incorporated by reference herein.

1341. Conceptus and Bayer had duties to establish and maintain procedures for

implementing CAPAs under 21 C.F.R. § 820.100. Conceptus and Bayer breached these duties as stated in this Complaint, specifically the First Cause of Action, Second Cause of Action, Third Cause of Action and Fourth Cause of Action, which are incorporated by reference herein.

2. Conceptus and Bayer Failed to Ccomply with FDA Approval of Essure®, Resulting in a “Manufacturing Defect” of the Device.

1342. Conceptus and Bayer also violated federal law in the manufacture of Essure® in that they:

- used non-conforming material;
- failed to use pre-sterile and post-sterile cages;
- manufactured Essure® at an unlicensed facility;
- manufactured Essure® for three years without a license to do so;
- failed to analyze or identify existing potential causes of non-conforming product and other quality problems;
- failed to track the non-conforming product;
- failed to follow procedures used to control products which did not conform to specifications;
- failed to have complete Design Failure Analyses; and
- failed to document CAPA activities for a supplier correction action;

1343. The original design for a Class III medical device is the product that is approved by the FDA. This FDA approval includes not only the physical components of the product, but the labeling and intended use of the product as well.

1344. Under federal regulations, a product that does not comply with the FDA approval is considered “adulterated” and/or “misbranded.” Under state law, a product that does not comply with the FDA approval is considered a “manufacturing defect.” Therefore, any product sold that is not in compliance with the FDA approval is both misbranded and/or adulterated under

federal law and a manufacturing defect under state law. Therefore, the same underlying defect and/or actions of the manufacturer that have given rise to a federal violation are also a parallel state violation.

1345. Violating the conditions of approval for the FDA approval is another way of saying that the manufacturer violated the original design of the product and therefore creates a viable manufacturing defect claim.

1346. There are multiple manufacturing defects in the Essure® device that were implanted into Plaintiffs which caused Plaintiffs' device to migrate and/or break/fracture apart and/or caused Plaintiffs to experience heavy menstrual cycle bleeding and long-term chronic pain amongst other side effects, all which became known to Conceptus and Bayer, including but not limited to:

- The stainless steel used in the device became unpassivated, which can cause the device to rust;
- the nitinol could have a nickel rich oxide which the body attacks;
- the no lead solder could in fact have trace lead in it;
- the Galvanic action between the metals used to manufacture Essure®, which causes the encapsulation of the product within the fallopian tubes, could be a continuous irritant to some patients;
- the nitinol in the device can degrade due to High Nickel Ion release, increasing the toxicity of the product for patients;
- latent manufacturing defects such as cracks, scratches, and other disruption of the smooth surface of the metal coil, may have existed in the finished product, causing excess nickel to leach into the surrounding tissues after implantation;
- PET fibers degrade at 65 degrees, therefore considerable degradation is expected at 98 degrees in the human body and degradation products of the PET used in the implant can be toxic to patients, inciting both chronic inflammation and possible autoimmune issues;

- the mucosal immune response to nickel is different than the immune response in non-mucosal areas of the body;
- there was an inadequate solder joint between the inner and outer coils of the micro-insert which can cause the micro-insert to fracture/break apart, and which Conceptus and Bayer admit is or could be a reason for device breakage, and;
- the central axis was not fully adhered to the spring which can cause the micro- insert to fracture/break apart, and which Conceptus and Bayer admit is or could be a reason for device breakage.

1347. The Essure[®] device implanted in Plaintiffs was not reasonably safe for its intended uses and was defective as described herein as a matter of law with respect to its manufacture, in that it deviated materially from Conceptus and Bayer's design and manufacturing specifications in such a manner as to pose unreasonable increased risks of serious bodily harm to Plaintiffs.

1348. The Essure[®] devices manufactured and sold by Conceptus and Bayer and implanted into Plaintiffs were defective in manufacture because they did not comply with Conceptus' and Bayer's own design specifications, used non-conforming material, and deviated from otherwise identical units from the same product line, manufactured with the same specifications.

1349. At all times mentioned herein, Conceptus and Bayer placed Essure[®] on the market and supplied the Essure[®] device used during Plaintiffs' permanent sterilization procedures.

1350. Conceptus and Bayer have a duty to manufacture the Essure[®] device consistent with the specifications, requirements, federal regulations, PMA, and/or conditions of approval.

1351. At the time the Essure[®] devices left control of Conceptus and Bayer when they were implanted into Plaintiffs, they were unreasonably dangerous due to non-compliance by

both companies with the FDCA, and the regulations promulgated pursuant to it.

B. THERE IS A CAUSAL AND FACTUAL NEXUS BETWEEN PLAINTIFFS' INJURIES AND DEFENDANTS' BREACH OF ITS STATE LAW DUTIES AND IDENTICAL FEDERAL REQUIREMENTS.

1352. Conceptus and Bayer breached their identical state and federal duties, as alleged in all prior Counts of this Complaint, and incorporated by reference herein.

1353. Since Conceptus and Bayer failed to meet their duties under the above mentioned federal and parallel state laws, Plaintiffs and Plaintiffs' treating physicians did not know and had no reason to know that Essure[®] was causing Plaintiffs' injuries.

1354. As such, Plaintiffs and Plaintiffs' treating physicians could not properly and/or timely diagnose the cause of Plaintiffs' injuries, which caused and/or contributed to Plaintiffs having to endure prolonged and unnecessary pain and suffering.

1355. As a direct and proximate result of Defendants' violations of one or more of the above mentioned federal statutory and regulatory standards of care, Essure[®] was implanted in Plaintiffs and Plaintiffs were caused to endure a serious injury, as defined in 21 C.F.R. § 803.3.

1356. Plaintiffs were caused to suffer, and will suffer in the future, injuries including, but not limited to pain, suffering, lost wages, disability, disfigurement, legal obligations for hospital, medical, nursing, rehabilitative, and other medical services and treatment.

WHEREFORE, Plaintiffs respectfully demand judgment in an amount in excess of the Arbitration limits in Allegheny County against all Bayer Defendants, and each of them, individually, jointly and severally, and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

- A) compensatory damages for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;

- B) for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;
- C) for specific damages according to proof;
- D) for Punitive and Exemplary damages according to proof;
- E) for pre-judgment interest and post-judgment interest as allowed by law;
- F) for reasonable attorneys' fees;
- G) for the costs of these proceedings; and
- H) for such other and further relief as this Court deems just and proper.

A JURY TRIAL IS DEMANDED.

NINTH CAUSE OF ACTION
Violation of Pennsylvania Unfair Trade Practices and
Consumer Protection Law (UTCPL)
73 P.S. § 201-1 et seq.

1357. Plaintiffs repeat and incorporate by reference all other paragraphs of this Petition as if fully set forth herein and further allege as follows:

1358. Conceptus and Bayer had a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Essure® product.

1359. More specifically, Plaintiffs incorporate by reference herein the allegations stated in the Second Cause of Action, Section D (1-3), and in the Fourth Cause of Action, Section D (1-3), both above.

1360. Conceptus and Bayer engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs for Essure® that would not have been paid had Conceptus and Bayer not engaged in unfair and deceptive conduct.

1361. Conceptus and Bayer engaged in unfair methods of competition or deceptive acts or practice that were proscribed by law, including the following:

- A) Representing that goods or services have characteristic ingredients, uses, benefits or quantities that they do not have;
- B) Advertising goods or services with the intent not to sell them as advertised; and
- C) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

1362. Conceptus' and Bayer's conduct constitutes "unfair methods of competition" and "unfair or deceptive acts or practices" under 73 P.S. § 201-2(4)(v) and § 201-2(4)(xxi). Furthermore, such conduct is unlawful pursuant to 73 P.S. § 201-3.

1363. Plaintiffs are consumers of goods and services within the scope of Pennsylvania's Consumer Protection Law and are entitled to bring an action for damages suffered pursuant to 73 P.S. § 201-9.2.

1364. Conceptus and Bayer are the supplier, manufacturer, advertiser, and seller, who are subject to liability under 73 P.S. § 201-1 *et seq.* for unfair, deceptive, false, and misleading consumer sales practices.

1365. Conceptus' and Bayer's deceptive and fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted unfair, misleading, deceptive or false acts or practices in the conduct of trade or commerce in violation of 73 P.S. § 201-1 *et seq.*

1366. Conceptus and Bayer violated the state statutes that were enacted to protect consumers against unfair, deceptive, false and misleading trade practices and false advertising, by knowingly and falsely representing that the Essure[®] product was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

1367. Conceptus and Bayer had actual knowledge of the defective and unreasonably dangerous condition of Essure[®] and failed to take any action to cure such defective and dangerous conditions.

1368. Plaintiffs were injured by the cumulative and indivisible nature of Conceptus' and Bayer's conduct. The cumulative effect of Conceptus' and Bayer's conduct directed at patients, physicians and consumers was to create demand for and sell Essure[®]. Each aspect of Conceptus' and Bayer's conduct combined to artificially create sales of Essure[®].

1369. Plaintiffs purchased and used the Essure[®] device for personal use and suffered ascertainable losses as a result of Conceptus' and Bayer's actions in violation of 73 P.S. § 201-1 *et seq.*

1370. Had Conceptus and Bayer not engaged in the deceptive conduct described herein, Plaintiffs' physicians could not have used Essure[®] and Plaintiffs would not have purchased and/or paid for Essure[®] and would not have incurred related medical costs and injury.

1371. Plaintiffs' physician relied upon Conceptus' and Bayer's misrepresentations and material omissions in determining whether to use Essure[®].

1372. Bayer's conduct and acts of unfair competition are ongoing and present a continuing threat of harm to the general public.

1373. By reason of unlawful acts engaged in by Conceptus and Bayer, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

1374. As a direct and proximate result of Conceptus' and Bayer's violations of the state consumer protection laws cited herein, Plaintiffs have sustained economic losses and other damages and are entitled to statutory and compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs respectfully demand judgment in an amount in excess of the Arbitration limits in Allegheny County against all Bayer Defendants, and each of them, individually, jointly and severally, and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

- A) compensatory damages for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;
- B) for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;
- C) for specific damages according to proof;
- D) for Punitive and Exemplary damages according to proof;
- E) for pre-judgment interest and post-judgment interest as allowed by law;
- F) for reasonable attorneys' fees;
- G) for the costs of these proceedings; and
- H) for such other and further relief as this Court deems just and proper.

A JURY TRIAL IS DEMANDED.

Respectfully Submitted:

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Date: August 1, 2018

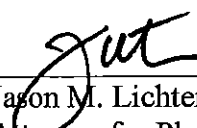
VERIFICATION OF COUNSEL

JASON M. LICHTENSTEIN, ESQUIRE, says that he is the attorney for Plaintiffs, and that he is authorized to make this statement and that the facts contained herein are true and correct to the best of his information, knowledge and belief. The verification of counsel is being attached hereto in lieu of that of Plaintiffs because of the inability to obtain a Verification from Plaintiffs in the time required to file this COMPLAINT IN CIVIL ACTION.

This statement is made subject to the penalties of 18 Purdons Consolidated Statutes Section 4904 relating to unsworn falsification to authorities.

EDGAR SNYDER & ASSOCIATES, LLC

By: _____


Jason M. Lichtenstein, Esquire
Attorney for Plaintiffs

Date: _____

8/1/18

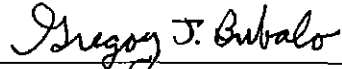
VERIFICATION OF COUNSEL

GREGORY J. BUBALO, ESQUIRE, says that he is the attorney for Plaintiffs, and that he is authorized to make this statement and that the facts contained herein are true and correct to the best of his information, knowledge and belief. The verification of counsel is being attached hereto in lieu of that of Plaintiffs because of the inability to obtain a Verification from Plaintiffs in the time required to file this COMPLAINT IN CIVIL ACTION.

This statement is made subject to the penalties of 18 Purdons Consolidated Statutes Section 4904 relating to unsworn falsification to authorities.

BUBALO GOODE PLC

By: _____



Gregory J. Bubalo, Esquire
Attorney for Plaintiffs


Date: August 1, 2018

CERTIFICATE OF COMPLIANCE

I certify that this filing complies with the provisions of the *Public Access Policy of the Unified Judicial System of Pennsylvania: Case Records of the Appellate and Trial Courts* that require filing confidential information and documents differently than non-confidential information and documents.

Submitted by:

EDGAR SNYDER & ASSOCIATES, LLC



Jason M. Lichtenstein, Esquire
Attorney No.: 73288